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In re application of

GILSON, Paul, et al.

Appln. No.: 10/058,828

Group Art Unit: 3731

Confirmation No.: 3776

Examiner: Uyen T. Ho

Filed: January 30, 2002

For: EMBOLIC PROTECTION DEVICE

PAPER(S) FILED ENTITLED:

1. Suggestion for Interference Under 37 C.F.R. § 41.202(A)
2. Petition for Extension of Time (In Duplicate)
3. Declaration of Paul Gilson, Eamon Brady, Padraig Maher, David Vale, and Chas Taylor
4. Declaration of Mairsil Claffey
5. Declaration of John O'Shaughnessy
6. Declaration of Dr. Gary Roubin
7. Exhibits 1-3, 5, 7-75, 77-79, 81-88 and 90-109

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

GILSON ET AL.

APPLN. NO.: 10/058,828

CONFIRMATION NO.: 3776

FILED: JANUARY 30, 2002

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EXAMINER: UYEN T. HO

SUGGESTION FOR INTERFERENCE UNDER 37 C.F.R. §41.202(A)

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Sir:

In response to the Office Action dated September 21, 2005, and pursuant to 37 C.F.R. §41.202(a), Applicants suggest an interference with pending U.S. Patent Application Serial No. 09/723,003, filed November 27, 2000, naming as inventors Thomas E. Broome, John M.K. Daniel, and Thomas R. Hecktner. A Petition for Extension of Time is being currently filed herewith.

A notice of allowance was mailed in the Broome '003 application on April 20, 2005, and the issue fee was paid on July 19, 2005. Pursuant to MPEP §2305.04, Applicants respectfully request that the Broome '003 application be withdrawn from issuance, if necessary, to permit consideration of the present suggestion for interference. Withdrawal from issuance of the Broome '003 application is required, because for the reasons stated below, the Broome '003 application contains claims to the same or substantially the same inventions as Applicants' claims, and the present Applicants are *prima facie* first inventors of the subject matter of the proposed counts.

Pursuant to 37 C.F.R. §41.202(a)(4), Applicants will prevail on priority because Applicants' parent application Ser. No. 09/188,472, filed on November 11, 1998, constitutes a prior constructive reduction to practice of the subject matter of the proposed counts. Broome's Application Ser. No. 09/723,003 was filed on November 27, 2000, which is after the filing date of Applicants' parent application. Although Broome's Ser. No. 09/723,003 is a continuation of Ser. No. 09/035,740, filed on March 5, 1998, for the reasons set forth below, Broome's parent application does not describe an anticipation of the subject matter of the proposed counts in compliance with §112, first paragraph, and therefore does not constitute an earlier constructive reduction to practice of the subject matter of the proposed counts under 37 C.F.R. §41.201.

Broome is not entitled to benefit of any earlier application referred to in the '003 application. Broome's parent application Ser. No. 09/035,740 (now U.S. Patent 6,152,946) was a continuation-in-part of U.S. Patent Application Ser. No. 08/943,358, filed October 3, 1997 (U.S. Patent 6,001,118). The '118 patent does not contain Figs. 17-20, which are the only disclosure of any filter element that is not permanently attached to the guidewire in the Broome '003 application. The '118 patent does not disclose a filter element in which rotation or distal translation of the guide wire relative to the filter element device does not displace the filter element, as required by both proposed counts.

As demonstrated by the attached declarations and exhibits, Applicants are also *prima facie* first inventors of the subject matter of the proposed counts, because they conceived of the subject matter of the counts prior to the filing date of Broome's parent application (March 5, 1998). Applicants were diligent from a date just prior to the filing of Broome's parent application, until Applicants' constructive reduction to practice on April 8, 1998, when Irish Application No. 98 0267 was filed.

Both Broome and the Applicants copied claims from two U.S. Patents issued to Bates. During prosecution of Ser. No. 09/723,003, Broome represented that Scimed Life Systems, Inc.,

which is the assignee of the Broome application, had purchased Bates Patent Nos. 6,179,859 B1 and 6,468,291 B2. Scimed Life Systems, Inc. proposed "to disclaim all claims of the two Bates *et al.* patents in order to remove these patents as impediments to issuance of Applicants' claims." Amendment dated April 1, 2005, page 7.

Broome's Application Ser. No. 09/723,003 cannot issue as a patent unless Scimed Lifesystems first disclaims all claims of the two Bates patents, as it proposed. If Scimed Lifesystems disclaims all claims of the two Bates patents, an interference between the present application and the two Bates patents will not be necessary. For this reason, although the Applicants bring the Bates patents to the attention of the Examiner, Applicants do not at this time request an interference between the present application and either of the Bates patents.

TABLE OF CONTENTS

I. Statement Pursuant to 37 C.F.R. §41.202(a)(1)

Pursuant to 37 C.F.R. §41.202(a)(1), Applicants identify the application with which the Applicants seek an interference as follows:

U.S. Patent Application Serial No. 09/723,003, filed November 27, 2000, naming as inventors Thomas E. Broome, John M.K. Daniel, and Thomas R. Hecktner.

II. Statement Pursuant to 37 C.F.R. §41.202(a)(2)

Pursuant to 37 C.F.R. §41.202(a)(2), Applicants identify all claims that are believed to interfere, propose counts, and show how the claims correspond to one or more counts, as follows.

A. Interfering Claims of the Parties

Applicants identify all claims of the parties that should be designated as corresponding to the counts, as follows:

Applicants' Claims 44, 48, 49, 53, 65, 67, 68, 85, 92, 93, 96, 97, 98 and 99.

Broome *et al.* Ser. No. 09/723,003 Claims 52, 53, 54, 55, 56, 57, 58, 60, 61, 62, and 63.

B. Proposed Counts

Applicants propose the following two counts for the interference:

Proposed Count 1

A method of filtering emboli from blood flowing through a vessel as claimed in Gilson Claim 97 or Broome Claim 56.

Gilson Claim 97 is compared with Broome Claim 56 in the following table:

Proposed Count 1	
Gilson Claim 97	**Broome Claim 56**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	A method of filtering emboli from blood flowing through a vessel, the method comprising:
providing a guide wire having a distal stop,	providing a guide wire having a distal region including a stop,
and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;
transluminally inserting the guide wire and filter element into a vessel;	transluminally inserting the guide wire and filter element into a vessel;
deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element.	rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.

As shown in the table, Gilson Claim 97 recites "a guide wire having a distal stop," while Broome Claim 56 recites "a guide wire having a distal region including a stop." Broome Claim 56 recites "rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element," while Gilson Claim 97 recites "rotation or distal translation of the guide wire relative to the filter element not displacing the filter element," thus encompassing any movement of the guidewire.

Using the two-way analysis required by 37 C.F.R. §41.202(a)(3), which defines interfering subject matter, "[a]n interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa." A two-way test is thus applied to determine whether interfering subject matter exists. Applicants submit that Gilson Claim 97 and Broome Claim 56 define interfering subject matter. Broome Claim 56 anticipates Gilson Claim 97. It is obvious that movement of the guidewire could be caused by advancing a treatment device along the guide wire, as recited in both claims, and Gilson Claim 97 thus makes Broome Claim 56 obvious.

Although Gilson Claim 97 is broader than Broome Claim 56, applicants submit that the count should include Gilson Claim 97, because the applicants claim this broader subject matter and it encompasses their best priority proofs.

Proposed Count 2

A method of filtering emboli from blood flowing through a vessel as claimed in Gilson Claim 98 or Broome Claim 62.

Gilson Claim 98 is compared with Broome Claim 62, which includes the limitations of independent Broome Claim 61, in the following table:

Proposed Count 2 Gilson Claim 98 or Broome Claim 62	
Gilson Claim 98	**Broome Dependent Claim 62**
98. A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal region including a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	61. A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal region including a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.
	62. The method of claim 61 further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.

Broome Claim 62 recites "rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element," while Gilson Claim 98 recites "rotation or distal translation of the guide wire relative to the filter element not displacing the filter element," thus encompassing any movement of the guidewire.

Using the two-way analysis required by 37 C.F.R. §41.202(a)(3), Gilson Claim 98 and Broome Claim 62 define interfering subject matter. Broome Claim 62 anticipates Gilson Claim 98. It is obvious that movement of the guidewire could be caused by advancing a treatment device along the guide wire, as recited in both claims, and Gilson Claim 98 thus makes Broome Claim 62 obvious.

Although Gilson Claim 98 is broader than Broome Claim 62, applicants submit that the count should include Gilson Claim 98, because the applicants claim this broader subject matter and it encompasses their best priority proofs.

Under the 2004 rules, it is not required that a count be as broad as the broadest patentable claims of the parties, and apparatus claims are properly designated as corresponding to method counts if the structural limitations of the method count anticipate or make obvious the structural limitations of apparatus claims. The method counts proposed by Applicants are appropriate, because each count defines a patentably distinct invention. The additional structure and step recited in proposed Count 2, including the self-expanding filter and the step of retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element, are neither anticipated by nor obvious from the method recited in Count 1.

The advantage of method Counts 1 and 2 is that they anticipate many of the broader apparatus claims, thus simplifying claim designation, as discussed below.

The two patentably distinct proposed counts correspond to claims of the two issued Bates patents. Count 1 corresponds substantially to Claim 21 of Bates U.S. Patent 6,179,859. Count 2 corresponds substantially to Claim 18 of Bates U.S. Patent 6,468,291.

C. Corresponding Claims of the Parties

Applicants show how the claims correspond to the counts, as follows. Under 37 C.F.R. §41.207(b)(2), a claim corresponds to a count if the subject matter of the count, treated as prior art to the claim, would have anticipated or rendered obvious the subject matter of the claim. Claim correspondence is thus determined using a one-way test, and the parties' claims are properly designated as corresponding to a count, even though they may not each interfere with a claim of an opponent.

The claims of the parties which should be designated as corresponding to the counts are as follows:

Claims Corresponding to Count 1:

Applicants' Claims 49, 53, 65, 67, 68, and 97.

Broome *et al.* Ser. No. 09/723,003: Claims 53, 54, 55, 56, 57, and 58.

Claims Corresponding to Count 2:

Applicants' Claims 44, 48, 85, 92, 93, 96, 98 and 99.

Broome *et al.* Ser. No. 09/723,003: Claims 52, 60, 61, 62, and 63.

These claims are set forth in the attachment at Tab 1 for the convenience of the examiner.

Applicants submit that each of the parties' claims is anticipated by or obvious in view of the proposed counts, assuming that the counts are prior art, as shown in the following tables. Applicants do not admit that any of their claims are anticipated by or *prima facie* obvious from

anything other than the counts proposed herein and, even then, only for the limited purpose of determining designation of the parties' claims. Thus, the statements made herein should not be construed as an admission that any of the Gilson claimed subject matter lacks novelty and/or is obviousness.

Claims requiring a self-expanding filter, or a filter comprising self-expanding struts, are properly designated as corresponding to Count 2. Claims reciting the step of retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element are also properly designated as corresponding to Count 2.

D. Claims Corresponding to Proposed Count 1

1. Gilson Claim 97 and Broome Claim 56

Because the methods recited in Gilson Claim 97 and Broome Claim 56 are incorporated in proposed Count 1, these claims are necessarily anticipated by proposed Count 1.

Proposed Count 1 Gilson Claim 97 or Broome Claim 56	
Gilson Claim 97	**Broome Claim 56**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	A method of filtering emboli from blood flowing through a vessel, the method comprising:
providing a guide wire having a distal stop,	providing a guide wire having a distal region including a stop,
and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;
transluminally inserting the guide wire and filter element into a vessel;	transluminally inserting the guide wire and filter element into a vessel;

deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element.	rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.

2. Gilson Claim 65

Gilson Claim 65 is anticipated by Broome Claim 56, and is therefore properly designated as corresponding to Count 1.

3. Gilson Claim 67 and Broome Claim 57

Applicants submit that the method claimed in Gilson Claim 67 and Broome Claim 57 is obvious in view of the method recited in proposed Count 1.

Dependent Gilson Claim 67 and Broome Claim 57 recite that the method further comprises providing a delivery sheath, and compressing the filter element to a contracted state to insert the filter element within the delivery sheath.

Count 1 recites the steps of transluminally inserting the guide wire and filter element into a vessel, and deploying the filter element to engage a wall of the vessel. Assuming that Count 1 is prior art, the use of a delivery sheath to transluminally insert the contracted filter element into a vessel is obvious.

4. Gilson Claim 68 and Broome Claim 58

Applicants submit that the method claimed in Gilson Claim 68 and Broome Claim 58 is obvious in view of the method recited in proposed Count 1.

Dependent Gilson Claim 68 and Broome Claim 58 recite that the filter element comprises an expandable sac, and that deploying the filter element comprises expanding the expandable sac so that a perimeter of the expandable sac contacts the wall of the vessel.

Count 1 recites the steps of transluminally inserting the guide wire and filter element into a vessel, and deploying the filter element to engage a wall of the vessel. Assuming that Count 1 is prior art, the expansion of the filter element to engage a wall of the vessel, and an expandable filter sac, are obvious.

5. Broome Claim 53

Applicants submit that the apparatus claimed in Broome Claim 53 is obvious, assuming that the apparatus used in the method recited in proposed Count 1 is prior art, as shown in the following table.

A "guide wire having a distal stop" as recited in Count 1 anticipates or makes obvious "a guide wire having a first portion having a first diameter and a distal region having a second diameter greater than the first diameter" as recited in Broome Claim 53. In order for the distal "stop" to function as a "stop," it must have a diameter that is greater than the aperture in the capture ring, and this limitation of Claim 53 is inherent or obvious. In order for the capture ring to translate on the guidewire, the capture ring must have an aperture greater than the first diameter, and this limitation of Claim 53 is inherent or obvious.

Proposed Count 1 (Gilson Claim 97)	**Broome Claim 53**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	53. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:
providing a guide wire having a distal stop,	a guide wire having a first portion having a first diameter and a distal region having a second diameter greater than the first diameter; and
and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	a filter element having a capture ring disposed for translation on the first portion, the capture ring having an aperture greater than the first diameter but smaller than the second diameter,
transluminally inserting the guide wire and filter element into a vessel;	
deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element.	wherein rotation or distal translation of the guide wire relative to the capture ring does not displace the filter element.

6. Gilson Claim 49 and Broome Claim 54

Applicants submit that the apparatus claimed in Gilson Claim 49 and Broome Claim 54 is obvious in view of the proposed Count 1.

These dependent claims further recite that in the apparatus of Gilson Claim 48 and Broome Claim 54, the filter element comprises an expandable sac.

Assuming that Count 1 is prior art, it is anticipated or obvious to use an expandable sac in a filter element which is deployed to engage a wall of the vessel after being transluminally inserted in the vessel.

7. Gilson Claim 53 and Broome Claim 55

Applicants submit that the apparatus claimed in Gilson Claim 53 and Broome Claim 55 is obvious in view of proposed Count 1.

These dependent claims recite that the guide wire further comprises a flange disposed on the distal region having a diameter larger than the diameter of the aperture in the capture ring. Assuming Count 1 is prior art, it is obvious to use a flange having a diameter larger than the aperture in the filter support ring to limit distal translation of the filter element in a distal direction.

E. Claims Corresponding to Proposed Count 2

Proposed Count 2 contains two additional limitations not present in Count 1. Count 2 recites that the filter element comprises a plurality of self-expanding struts having a filter sac affixed thereto. Proposed Count 2 also recites the additional step of retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.

Under 37 C.F.R. §41.207(b)(2), a claim corresponds to a count if the subject matter of the count, treated as prior art to the claim, would have anticipated or rendered obvious the subject matter of the claim.

Proposed Count 2 Gilson Claim 98 or Broome Claim 62	
Gilson Claim 98	**Broome Dependent Claim 62**
98. A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal region including a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	61. A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal region including a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.
	62. The method of claim 61 further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.

Gilson Claim 98 and Broome Claim 62 are incorporated in proposed Count 2, and should be designated as corresponding to proposed Count 2.

1. Gilson Claim 44

Applicants submit that the apparatus claimed in Gilson Claim 44 is obvious, assuming that the apparatus used in the method recited in proposed Count 2 is prior art, as shown in the following table.

Gilson Claim 44 recites a "capture ring" disposed for translation on the guide wire. Assuming that a filter element disposed for translation on the guide wire recited in Count 2 is prior art, it is obvious to attach the plurality of self-expanding struts to a supporting ring or tube of the filter element. Such a support permits translation of the filter element on the guidewire proximal to the distal stop, and limits translation of the filter element in a distal direction.

Proposed Count 2 (Gilson Claim 98)	**Gilson Claim 44**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	44. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:
providing a guide wire having a distal region including a distal stop,	a guide wire having a distal region and a stop on the distal region;
and a filter element disposed for translation on the guide wire proximal to the distal stop,	a capture ring disposed for translation on the guide wire, the stop limiting translation of the capture ring in a distal direction;
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	and a self-expanding filter sac connected to the capture ring;
transluminally inserting the guide wire and filter element into a vessel;	

deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	wherein, when the filter sac is deployed in the vessel,
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	rotation or distal translation of the guide wire relative to the capture ring does not displace the filter sac,
further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	but retraction of the guide wire in a proximal direction causes the stop to abut against the capture ring.

2. Broome Claim 52

Applicants submit that the apparatus claimed in Broome Claim 52 is obvious, assuming that the apparatus used in the method recited in proposed Count 2 is prior art, as shown in the following table.

Broome Claim 52 recites a "capture ring" disposed for translation on the guide wire. This limitation is obvious, assuming that a filter element disposed for translation on the guide wire recited in Count 2 is prior art, because it is obvious to attach the plurality of self-expanding struts to a supporting ring or tube of the filter element. Such a support permits translation of the filter element on the guidewire proximal to the distal stop, and limits translation of the filter element in a distal direction.

Proposed Count 2 (Gilson Claim 98)	**Broome Claim 52**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	52. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:
providing a guide wire having a distal region including a distal stop,	a guide wire having a distal region and a stop on the distal region;
and a filter element disposed for translation on the guide wire proximal to the distal stop,	a capture ring disposed for translation on the guide wire, the stop limiting translation of the capture ring in a distal direction;
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	and a filter sac connected to the capture ring;
transluminally inserting the guide wire and filter element into a vessel;	
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	wherein, when the filter sac is deployed in the vessel,
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	rotation or distal translation of the guide wire relative to the capture ring does not displace the filter sac,
further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	but retraction of the guide wire in a proximal direction causes the stop to abut against the capture ring.

3. Gilson Claim 48

Applicants submit that the apparatus claimed in Gilson Claim 48 is obvious, assuming that the apparatus used in the method recited in proposed Count 2 is prior art, as shown in the following table.

Gilson Claim 48 recites a "capture ring" disposed for translation on the guide wire. This limitation is obvious, assuming that a filter element disposed for translation on the guide wire recited in Count 2 is prior art, because it is obvious to attach the plurality of self-expanding struts to a supporting ring or tube of the filter element. Such a support permits translation of the filter element on the guidewire proximal to the distal stop, and limits translation of the filter element in a distal direction. It is obvious that a guidewire having a larger distal diameter will function as a distal "stop," when the distal region of the guidewire has a diameter greater than the aperture in the ring supporting the filter.

A "guide wire having a distal stop" as recited in Count 2 anticipates or makes obvious "a guide wire having a first portion having a first diameter and a distal region having a second diameter greater than the first diameter" as recited in Gilson Claim 48, because a stop necessarily has a diameter greater than the diameter of the guidewire on which the filter element translates.

Proposed Count 2 (Gilson Claim 98)	**Gilson Claim 48**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	48. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:
providing a guide wire having a distal region including a distal stop,	a guide wire having a first portion having a first diameter and a distal region having a second diameter greater than the first diameter; and
and a filter element disposed for translation on	a self-expanding filter element having a

the guide wire proximal to the distal stop, the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element not displacing the filter element; further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	capture ring disposed for translation on the first portion, the capture ring having an aperture greater than the first diameter but smaller than the second diameter, wherein rotation or distal translation of the guide wire relative to the capture ring does not displace the filter element.

4. Gilson Claim 85

Because the apparatus recited in Gilson Claim 85 is anticipated by the apparatus used in proposed Count 2, this claim is properly designated as corresponding to proposed Count 2.

Proposed Count 2 (Gilson Claim 98)	**Gilson Claim 85**
A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal region including a distal stop,	85. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising: a guide wire having a distal stop;

and a filter element disposed for translation on the guide wire proximal to the distal stop,	a filter element disposed for rotation on a distal region of the guide wire,
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	the filter element comprising a self-expanding strut and a filter sac connected to the self-expanding strut; and the distal stop disposed on the distal region distal to the filter element, the distal stop limiting distal translation of the filter element on the guide wire;
transluminally inserting the guide wire and filter element into a vessel;	
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	wherein, when the filter sac is deployed in the vessel,
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	rotation of the guide wire does not displace the filter element.
further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	

5. Broome Claim 60

Because the apparatus recited in Broome Claim 60 is anticipated by the apparatus used in proposed Count 2, this claim is properly designated as corresponding to proposed Count 2.

Proposed Count 2 (Gilson Claim 98)	**Broome Claim 60**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	60. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:
providing a guide wire having a distal region including a distal stop,	a guide wire having a distal region;
and a filter element disposed for translation on the guide wire proximal to the distal stop,	a filter element disposed for rotation on the distal region of the guide wire,
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	the filter element comprising a self-expanding strut and a filter sac connected to the self-expanding strut; and a distal stop disposed on the distal region distal to the filter element, the distal stop limiting distal translation of the filter element on the guide wire;
transluminally inserting the guide wire and filter element into a vessel;	
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	wherein, when the filter sac is deployed in the vessel,
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	rotation of the guide wire does not displace the filter element.
further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	

6. Gilson Claim 92

Because Gilson Claim 92 is anticipated by proposed Count 2, this claim is properly designated as corresponding to proposed Count 2.

Proposed Count 2 (Broome Claim 62)	**Gilson Claim 92**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	92. A method of filtering emboli from blood flowing through a vessel, the method comprising:
providing a guide wire having a distal region including a distal stop,	providing a guide wire having a distal stop,
and a filter element disposed for translation on the guide wire proximal to the distal stop,	and a filter element disposed for translation on the guide wire proximal to the distal stop,
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;
transluminally inserting the guide wire and filter element into a vessel;	transluminally inserting the guide wire and filter element into a vessel;
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,
rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element;	rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.
further comprising retracting the guide wire in	

a proximal direction to cause the distal stop to abut against the filter element.	

7. Broome Claim 61

Because Broome Claim 61 is anticipated by proposed Count 2, this claim is properly designated as corresponding to proposed Count 2.

Proposed Count 2 (Broome Claim 62)	**Broome Claim 61**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	61. A method of filtering emboli from blood flowing through a vessel, the method comprising:
providing a guide wire having a distal region including a distal stop,	providing a guide wire having a distal region including a distal stop,
and a filter element disposed for translation on the guide wire proximal to the distal stop,	and a filter element disposed for translation on the guide wire proximal to the distal stop,
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;
transluminally inserting the guide wire and filter element into a vessel;	transluminally inserting the guide wire and filter element into a vessel;
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,
rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter	rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter

element; further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	element.

8. Gilson Claim 93 and Broome Claim 62

Because Gilson Claim 93 and Broome Claim 62 are identical to Broome Claim 62 incorporated in proposed Count 2, these claims are properly designated as corresponding to proposed Count 2.

9. Gilson Claim 96 and Broome Claim 63

Applicants submit that the method claimed in Gilson Claim 96 and Broome Claim 63 is obvious in view of the method and apparatus recited in proposed Count 2.

Gilson's dependent Claim 96, which depends from Claim 92, recites that the method further comprises providing a retrieval catheter having a pod, and advancing the retrieval catheter over the guide wire until the pod covers a mouth of the filter element, and urging the retrieval catheter against the self-expanding struts of the filter element to cause the filter element to collapse.

Broome's dependent Claim 63 recites that the method further comprises providing a retrieval catheter having a recovery sock, and advancing the retrieval catheter over the guide wire until the recovery sock covers a mouth of the filter element, and urging the retrieval catheter against the self-expanding struts of the filter element to cause the filter element to collapse.

10. Gilson Claim 99

Applicants submit that the method claimed in Gilson Claim 99 is obvious in view of the method and apparatus recited in proposed Count 2.

Gilson's dependent Claim 99 is an independent claim, which like Claim 96 recites that the method further comprises providing a retrieval catheter having a pod, and advancing the retrieval catheter over the guide wire until the pod covers a mouth of the filter element, and urging the retrieval catheter against the self-expanding struts of the filter element to cause the filter element to collapse. Gilson Claim 99 is identical to Gilson dependent Claim 96, except that independent Claim 92 requires "rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element," while Claim 99 recites "rotation or distal translation of the guide wire relative to the filter element not displacing the filter element," thus encompassing any movement of the guidewire.

Applicants submit that Gilson Claim 99 should be designated as corresponding to Count 2, for the same reasons that Gilson Claim 96 should be designated as corresponding to Count 2.

III. Statement Pursuant to 37 C.F.R. §41.202(a)(3)

Pursuant to 37 C.F.R. §41.202(a)(3), Applicants provide the following claim chart comparing at least one claim of each party corresponding to each count, and showing why the claims interfere within the meaning of §41.203(a). Under §41.202(a)(3), which defines interfering subject matter, "[a]n interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa." A two-way test is thus applied to determine whether interfering subject matter exists. For an interference to be declared, it is only necessary that a single claim of one party must interfere with a single claim of the other party.

Gilson Claim 97 and Broome Claim 56, which are incorporated in proposed Count 1, are discussed above, and define interfering subject matter. Gilson Claim 98, and Broome Claim 62,

which are incorporated in proposed Count 2, are discussed above, and define interfering subject matter.

In the tables, Broome's claims are the claims presented in the Amendment under 37 C.F.R. §1.116, dated April 1, 2005, in Ser. No. 09/723,003.

Interfering subject matter between the two applications clearly exists, because Applicants' Claim 93 is identical to dependent Broome Claim 62 (rewritten to include the limitations of independent Broome Claim 61), and these claims define interfering subject matter.

Gilson SN 10/058,828	**Broome SN 09/723,003**
93. A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal region including a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element;	61. A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal region including a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.
	62. The method of claim 61

further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.

The only difference between Applicants' Claim 65 and Broome's Claim 56 is that Applicants recite "a guide wire having a distal stop" while Broome recites "a guide wire having a distal region including a stop." Each claim anticipates the other, despite this difference in phrasing, since a guide wire which has a "distal stop" must also have a "distal region" which includes the "distal stop." The parties' dependent claims are identical, and also define interfering subject matter.

Gilson SN 10/058,828	**Broome SN 09/723003**
65. A method of filtering emboli from blood flowing through a vessel, the method comprising:	56. A method of filtering emboli from blood flowing through a vessel, the method comprising:
providing a guide wire having a distal stop,	providing a guide wire having a distal region including a stop,
and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;
transluminally inserting the guide wire and filter element into a vessel;	transluminally inserting the guide wire and filter element into a vessel;
deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,
rotation or distal translation of the guide wire	rotation or distal translation of the guide wire

relative to the filter element imparted by the treatment device not displacing the filter element.	relative to the filter element imparted by the treatment device not displacing the filter element.
67. The method of claim 65 further comprising: providing a delivery sheath; and compressing the filter element to a contracted state to insert the filter element within the delivery sheath.	57. The method of claim 56 further comprising: providing a delivery sheath; and compressing the filter element to a contracted state to insert the filter element within the delivery sheath.
68. The method of claim 65 wherein the filter element comprises an expandable sac, and deploying the filter element comprises expanding the expandable sac so that a perimeter of the expandable sac contacts the wall of the vessel.	58. The method of claim 56 wherein the filter element comprises an expandable sac, and deploying the filter element comprises expanding the expandable sac so that a perimeter of the expandable sac contacts the wall of the vessel.

The difference between Applicants' Claim 85 and Broome's Claim 60 is that Applicants recite "a guide wire having a distal stop" while Broome recites "a guide wire having a distal region" and "a distal stop disposed on the distal region." Each claim anticipates the other, despite this difference in phrasing, since a guide wire which has a "distal stop" must also have a "distal region" which includes the "distal stop" disposed on that region. The parties' dependent claims are identical, and also define interfering subject matter.

Gilson SN 10/058,828	**Broome SN 09/723,003**
85. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising: a guide wire having a distal stop; a filter element disposed for rotation on a distal region of the guide wire, the filter element	60. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising: a guide wire having a distal region; a filter element disposed for rotation on the distal region of the guide wire, the filter

comprising a self-expanding strut and a filter sac connected to the self-expanding strut; and	element comprising a self-expanding strut and a filter sac connected to the self-expanding strut; and
the distal stop disposed on the distal region distal to the filter element, the distal stop limiting distal translation of the filter element on the guide wire;	a distal stop disposed on the distal region distal to the filter element, the distal stop limiting distal translation of the filter element on the guide wire,
wherein, when the filter sac is deployed in the vessel, rotation of the guide wire does not displace the filter element.	wherein, when the filter sac is deployed in the vessel, rotation of the guide wire does not displace the filter element.

The difference between Applicants' Claim 92 and Broome's Claim 61 is that Applicants recite "a guide wire having a distal stop" while Broome recites "a guide wire having a distal region including a distal stop." Each claim anticipates the other, despite this difference in phrasing, since a guide wire which has a "distal stop" must also have a "distal region" which includes the "distal stop."

Applicants' dependent Claim 96 recites "a retrieval catheter having a "pod" while Broome dependent Claim 61 recites "a retrieval catheter having a recovery sock." The pod and the recovery sock perform the same function in this method step, and despite this difference in phrasing, the pod anticipates or makes obvious a recovery sock, and the recovery sock anticipates or makes obvious a pod.

Gilson SN 10/058,828	**Broome SN 09/723,003**
92. A method of filtering emboli from blood flowing through a vessel, the method comprising:	61. A method of filtering emboli from blood flowing through a vessel, the method comprising:
providing a guide wire having a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element comprising a plurality of self-	providing a guide wire having a distal region including a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element

expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.	comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.
96. The method of claim 92 further comprising: providing a retrieval catheter having a pod; advancing the retrieval catheter over the guide wire until the pod covers a mouth of the filter element; and urging the retrieval catheter against the self-expanding struts of the filter element to cause the filter element to collapse.	63. The method of claim 61 further comprising: providing a retrieval catheter having a recovery sock; advancing the retrieval catheter over the guide wire until the recovery sock covers a mouth of the filter element; and urging the retrieval catheter against the self-expanding struts of the filter element to cause the filter element to collapse.

IV. Statement Pursuant to 37 C.F.R. §41.202(a)(4)

Pursuant to 37 C.F.R. §41.202(a)(4), Applicants will prevail on priority because Applicants' parent application Ser. No. 09/188,472, filed on November 11, 1998, constitutes a

prior constructive reduction to practice of the subject matter of the proposed counts. Broome's Application Ser. No. 09/723,003 was filed on November 27, 2000, which is after the filing date of Applicants' parent application. Although Broome's Ser. No. 09/723,003 is a continuation of Ser. No. 09/035,740, filed on March 5, 1998, for the reasons set forth below, Broome's parent application does not describe an anticipation of the subject matter of the proposed counts in compliance with §112, first paragraph, and therefore does not constitute an earlier constructive reduction to practice of the subject matter of the proposed counts under 37 C.F.R. §41.201.

In an interference, the Applicants are therefore *prima facie* entitled to a judgment of priority of invention, based on their earlier constructive reduction to practice of the subject matter of both proposed counts, and the interference should be declared with the present Applicants as senior party.

A. Broome's Parent Application is Not a Constructive Reduction to Practice of the Subject Matter of Either Proposed Count

Under 37 C.F.R. §41.201, "*Constructive reduction to practice* means a described and enabled anticipation under 35 U.S.C. 102(g)(1) in a patent application of the subject matter of a count."

Each of the proposed counts recites a method in which the filter element is deployed to engage a wall of the vessel, and a treatment device is advanced along the guide wire, and recites "rotation or distal translation of the guide wire relative to the filter element not displacing the filter element."

Broome's parent application does not disclose a method or apparatus in which "rotation or distal translation of the guide wire relative to the filter element" does not displace the filter element when the filter element is deployed in the vessel, and does not anticipate this limitation of the proposed counts.

The only embodiment disclosed in Broome's parent application in which the filter element is not permanently attached to the guidewire is illustrated in Figs. 17-20, and is described at pages 18-19 of the specification. In this embodiment, the filter element or "protective device 230" must be attached to docking member 216, which is "rigidly coupled to wire" 210/212 (page 18, lines 7-8) *prior to deployment* of the filter element.

As shown in Broome Fig. 18, prior to deployment in vessel 60, "Device 230 is inserted in a low-profile collapsed condition via cooperation with sheath 64" (page 19, lines 7-8). In its collapsed, pre-deployment state, the device 230 in sheath 64 "is advanced over guidewire 210 to align cone 232 with docking member 216. Cone 232 is forced into channel 220 of docking member 216 until ring 242 snaps into groove 222 and is maintained therein." (page 19, lines 3-6).

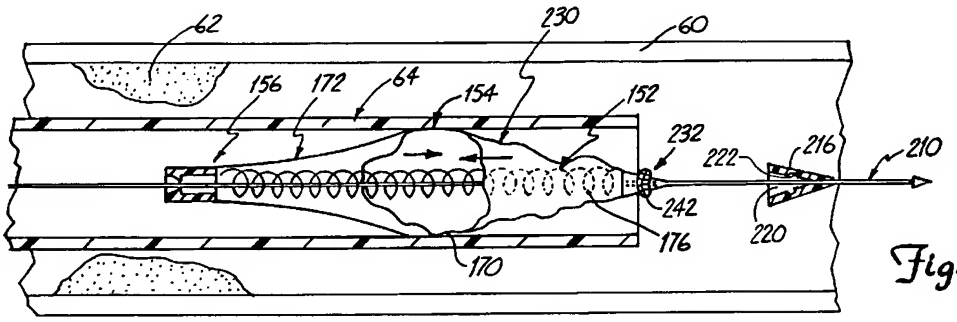

Fig. 18

Accordingly, *prior to deployment* in the vessel, the device 230 is affixed to the guidewire when the "locking ring" 242 (page 18, line 30) is snapped into the groove 222 of the docking member 216. Indeed, the Broome parent specification makes it clear that the device cannot be deployed from sheath 64 until the filter element is attached to the docking member, by explaining that "Device 230 is inserted in a low-profile collapsed condition via cooperation with sheath 64, and is deployed by withdrawing sheath 64 while maintaining the position of guidewire 210" after the device is positioned at a treatment site. (page 19, lines 7-11).

When the filter is deployed in the vessel, as shown in Broome Fig. 19, it is fixedly attached to guidewire 216 by the locking ring 242 in docking member 216.

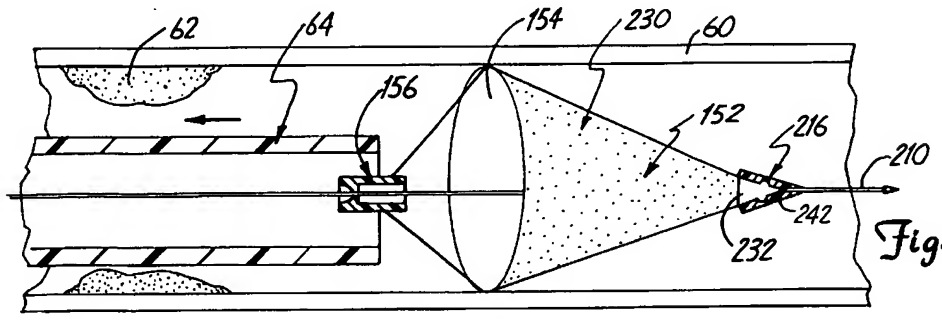

Fig. 19

It is clear from Broome's description that any rotation of the guidewire, or distal translation of the guidewire, when the filter element is deployed in the vessel, will necessarily displace the filter element.

For this reason, the description of device 230, which is the only embodiment in which the filter element is not permanently attached to the guidewire in Broome's parent application, does not anticipate the limitation of the proposed counts that when the filter element is deployed to engage a wall of the vessel, and a treatment device is advanced along the guide wire, "rotation or distal translation of the guide wire relative to the filter element not displacing the filter element."

Because Broome's parent application does not disclose an embodiment meeting these limitations of the proposed count in compliance with 35 U.S.C. §112, first paragraph, Broome's parent application does not constitute a constructive reduction to practice of the subject matter of the count under 37 C.F.R. §41.201. Broome is not entitled to the filing date of Broome's parent application in the interference.

V. APPLICANTS' PRIOR CONCEPTION AND DILIGENCE

A. Prior Conception of Count 1 by Applicants

Pursuant to 37 C.F.R. §41.202(a)(4), Applicants will prevail on priority because Applicants conceived the subject matter of proposed Count 1, on a date prior to Broome's parent application filing date (March 5, 1998), and were continuously diligent from a date prior to March 5, 1998, until their constructive reduction to practice of Count 1 by Irish Patent Application No. 98 0267, which was filed on April 8, 1998.

For the reasons set forth above, Broome's parent Application Ser. No. 09/035,740, filed on March 5, 1998, does not describe an anticipation of the subject matter of proposed Count 1 in compliance with §112, first paragraph, and therefore does not constitute an earlier constructive reduction to practice of the subject matter of proposed Count 1 under 37 C.F.R. §41.201. Even if Broome's parent application disclosed an anticipation of the subject matter of Count 1, which it does not, Applicants are *prima facie* entitled to priority of invention based on their earlier conception, prior to March 5, 1998, coupled by diligence to their constructive reduction to practice in Irish Application No. 98 0267, filed on April 8, 1998.

Broome is not entitled to benefit of any earlier application referred to in the '003 application. Broome's parent application Ser. No. 09/035,740 (now U.S. Patent 6,152,946) was a continuation-in-part of U.S. Patent Application Ser. No. 08/943,358, filed October 3, 1997 (U.S. Patent 6,001,118). The '118 patent does not contain Figs. 17-20, which are the only disclosure of any filter element that is not permanently attached to the guidewire in the Broome '003 application. The '118 patent does not disclose a filter element in which rotation or distal translation of the guide wire relative to the filter element device does not displace the filter element, as required by both proposed counts.

Prior to March 5, 1998, the inventors conceived of an embodiment meeting each limitation of Count 1, as demonstrated by the Declaration of Paul Gilson, Eamon Brady, Padraig Maher, David Vale, and Chas Taylor ("Gilson *et al.* Declaration"), ¶¶26-78; and corroborated by the Declaration of Mairsil Claffey ("Claffey Declaration"), ¶¶29-68; and the Declaration of John O'Shaughnessy ("O'Shaughnessy Declaration), ¶¶18-60.

B. Conception of Filter Element and Method Steps

Applicants' prior conception of the following limitations of Count 1 is disclosed and corroborated by their Irish Application No. 97 0789, filed on November 7, 1997 (of which benefit is claimed):

Irish Application No. 97 0789 discloses a filter element that provides a pathway for blood and has means for capturing and retaining undesired embolic material released during a surgical procedure (page 11, lines 19-24). IE '789 discloses a device that is used in an over the wire transcatheter configuration, in which the clinician will cross the lesion with a steerable guidewire (page 12, lines 3-5). IE '789 discloses a device that consists of a filter attached to a shaft that can run over the primary crossing guidewire (page 12, lines 11-13); the shaft being disposed for translation on the guide wire proximal of the distal end of the guidewire, for example, substrate shaft 33 in Figs. 11-15 and 18, which is threaded over a guidewire (page 16, lines 6-8). In accordance with IE '789, the clinician will cross the lesion with a steerable guidewire, and the filter is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 12, lines 4-8). In accordance with IE '789, the filter is deployed into the vessel and will capture emboli (page 12, lines 8-11); the deployed filter element will occlude the vessel except for the path or paths provided through the filter (page 12, lines 21-24). In accordance with IE '789, the deployed filter is placed distal to the site of the lesion being treated and will capture emboli that are generated or dislodged during balloon inflation and stent placement, a balloon and a stent being treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 12, lines 4-11; page 19, lines 10-17; Claims 23, 24).

Because in IE '789 the shaft or hollow support element (page 12, lines 14-18) on which the filter is mounted is not fixed to the guidewire (page 12, lines 11-13), rotation or distal translation of the guidewire relative to the filter element does not displace the filter element. The guidewire moves independently from the filter: it is first steered across the lesion, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). During retrieval, the filter can be withdrawn either with the guidewire or over it (page 16, lines 23-25). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the shaft thus does not displace the filter element.

(Gilson *et al.* Declaration, ¶¶26; Claffey Declaration, ¶29).

Prior to March 5, 1998, the inventors conceived of an embodiment shown in Exhibit 1, which is a page from the notebook of inventor David Vale that was made prior to March 5, 1998. (Gilson *et al.* Declaration, ¶¶28-40, Exhibit 1). Exhibit 1 shows an apparatus which the inventors conceived, that is used in the method of Count 1. This drawing is corroborated both by Irish Application No. 97 0789, and by the Claffey Declaration, ¶¶30-41, Exhibit 1 and the O'Shaughnessy Declaration, ¶¶19-31, Exhibit 1.

This drawing corroborates their invention of the following limitations of Count 1 (Gilson *et al.* Declaration, ¶41; Claffey Declaration, ¶42; O'Shaughnessy Declaration, ¶31):

Neurogard Details and Dims.
The CHRONOFLEX balloon filter is used in the method disclosed in Irish Application No. 97 0789, as shown, *e.g.*, in Fig. 18. Guidewire having a maximum shaft outer diameter (O.D.) of 0.014". The balloon filter is disposed on a polyimide tube having an inner diameter (I.D.) of 0.0145", and is thus disposed for translation on the guidewire proximal of the distal end of the guidewire. Exhibit 1 illustrates the filter polyimide tube support and guidewire extending from a

delivery catheter that is transluminally inserted into a vessel, as described in Irish Application No. 97 0789.

The self-expanding CHRONOFLEX filter is shown in deployed configuration, as described in Irish Application No. 97 0789, to engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed.

Treatment devices such as a balloon catheter or a stent balloon catheter disclosed in Exhibit 1 are inserted into a vessel to treat a portion of the vessel, and are advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789.

Because Exhibit 1 describes the inner lumen of the polyimide tube as having a diameter of 0.0145", and the guidewire has a maximum shaft outer diameter of 0.014", Exhibit 1 discloses that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element.

C. Conception and Corroboration of a Guidewire Having "A Distal Stop"

Prior to March 5, 1998, the applicants conceived of a dual-diameter or "stepped" guidewire with a distal end region having a diameter greater than the proximal diameter, which permits the filter element to translate distally and rotate on the guidewire proximal of the thicker distal end, but prevents translation of the filter distal to the thicker distal end, and thus is a stop within the scope of Count 1. (Gilson *et al.* Declaration, ¶41; Claffey Declaration, ¶42).

In the applicants' conception of the filter element shown in Exhibit 1, the polyimide tube on which the balloon filter is mounted is designed to rotate and distally translate on the guidewire, because the guidewire has a smaller diameter (0.014") than the inner lumen of the polyimide tube (0.0145"). (Gilson *et al.* Declaration, ¶42; Claffey Declaration, ¶43). Prior to March 5, 1998, the inventors realized that the small clearance between the guidewire and the polyimide tube caused undesirable friction between the guidewire and the tube. (Gilson *et al.* Declaration, ¶43; Claffey Declaration, ¶45).

In a conference call design review meeting prior to March 5, 1998, Chas Taylor, who is one of the inventors, referred to a solution to this problem by using a custom guidewire, having a thinner proximal portion on which the filter element polyimide tube support is mounted. (Gilson *et al.* Declaration, ¶45; Claffey Declaration, ¶46). Chas Taylor referred to using a stepped guidewire having a proximal diameter of 0.012″ and a distal end diameter of 0.018″. (Gilson *et al.* Declaration, ¶45; Claffey Declaration, ¶46). This conception is corroborated by an email describing the meeting, having a date before March 5, 1998, which was attended by inventors Chas Taylor, Padraig Maher, David Vale and Eamon Brady, and also by John O'Shaughnessy. (Gilson *et al.* Declaration, ¶46; Claffey Declaration, ¶47; Exhibit 3). The email was sent before March 5, 1998, to Susan Eighan and Mairsil Claffey.

Prior to March 5, 1998, the inventors appreciated that their invention of using a guidewire, having a distal end portion with a diameter greater than the inner diameter of the polyimide tube (0.0145″) would serve as a distal stop, which limits distal translation of the filter on the guidewire. (Gilson *et al.* Declaration, ¶47; Claffey Declaration, ¶48).

The inventors' appreciation of the distal stop function of the stepped guidewire is further corroborated by a memorandum describing a meeting of inventor Chas Taylor with Peter Gaines that took place prior to March 5, 1998 (Gilson *et al.* Declaration, ¶49; O'Shaughnessy Declaration, ¶¶37-38; Claffey Declaration, ¶49 (Exhibit 5). This document describes a question from vascular radiologist, Peter Gaines, asking how to remove the guidewire if the tip of the guidewire needs to be reformed, to permit better steering of the guidewire in the vessel if there is any difficulty in passing the lesion after the guidewire and filter are inserted in the vessel. The document states that because of the stepped guidewire configuration, it cannot be removed from the polyimide support of the filter element. (Gilson *et al.* Declaration, ¶49; O'Shaughnessy Declaration, ¶38). Chas Taylor indicated that the best solution was to remove both the filter and guidewire from the vessel, to reform the guidewire outside the vessel, and to transluminally reinsert both the guide wire and the filter into the vessel through the guiding catheter. (Gilson *et*

al. Declaration, ¶49; O'Shaughnessy Declaration, ¶38). The inventors clearly appreciated that the stepped guidewire is a distal stop, because it cannot be withdrawn proximally through the polyimide support of the filter element. (Gilson *et al.* Declaration, ¶51; O'Shaughnessy Declaration, ¶41; Claffey Declaration, ¶48). A copy of this memorandum was provided prior to March 5, 1998, to the inventors and to John O'Shaughnessy. (Gilson *et al.* Declaration, ¶52; O'Shaughnessy Declaration, ¶39).

Prior to March 5, 1998, the inventors decided that the optimal stepped guidewire configuration for use with a polyimide tube filter support having an inner diameter of 0.0145" was a custom guidewire having a proximal diameter of 0.013", which would permit rotation and distal translation of the filter on the proximal portion of the guidewire, and a distal end diameter of 0.016", which would act as a distal stop. (Gilson *et al.* Declaration, ¶51; Claffey Declaration, ¶41).

Their conception is corroborated by an order for the custom stepped 0.013"/0.016" guidewire, which was placed with a guidewire manufacturer, Lake Region Manufacturing Co., prior to March 5, 1998. This order is confirmed by a facsimile from Tom Kleist of Lake Region, dated prior to March 5, 1998, and an invoice from Lake Region, showing that the custom stepped 0.013"/0.016" guidewire was shipped to MedNova and received prior to March 5, 1998 (Gilson *et al.* Declaration, ¶52; O'Shaughnessy Declaration, ¶42; Exhibit 7).

Prior to March 5, 1998, the inventors and co-workers at MedNova constructed an embodiment of a filter device and system meeting each limitation of Count 1, as shown in photographs of a prototype "NeuroShield Mark 1" embolic filter protection system that was constructed prior to March 5, 1998. (Gilson *et al.* Declaration, ¶53; Claffey Declaration, ¶52; Exhibit 90). Exhibit 90 is a photograph of the prototype apparatus that is designed to be used in the method of Irish Application No. 97 0789 and Count 1. (Gilson *et al.* Declaration, ¶54; Claffey Declaration, ¶53).

This prototype apparatus corroborates the following (Gilson *et al.* Declaration, ¶54; Claffey Declaration, ¶50):

NeuroShield Mark 1 Prototype (Exhibit 90)
The filter system is used in the method disclosed in Irish Application No. 97 0789, where a representative filter is shown, *e.g.*, in Fig. 18. The balloon filter shown in Exhibit 90 is mounted on a polyimide tube support having an inner diameter of 0.0145", and the filter may be disposed for translation on a guidewire proximal of the distal stop of the guidewire. The polyimide tube support would prevent the filter from translating distal of the guidewire stop. The balloon filter is shown in Exhibit 90 in its deployed configuration, as described in Irish Application No. 97 0789, as it would engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed. Treatment devices such as a balloon catheter or a stent balloon catheter disclosed in Irish Application No. 97 0789 would be inserted into a vessel to treat a portion of the vessel, and would be advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789. The inner lumen of the polyimide tube filter support shown in Exhibit 90 has a diameter of 0.0145", and the proximal region of a guidewire for use therewith would have an outer diameter of 0.013". Exhibit 90 thus confirms that rotation or distal translation of the guide wire relative to the filter element would not displace the filter element. The guidewire can be translated through the filter polyimide tube support without displacing the filter element. The guidewire can also be rotated in the filter polyimide tube support without displacing the filter element. The filter system shown in Exhibit 90 would be used in the methods described in Irish Application 97 0789, in which the guidewire is first steered across the lesion, through the filter support, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the filter support shaft would not displace the filter element.

D. Conception and Corroboration of a Filter Having "A Capture Ring"

A filter element mounted on a ring or tube disposed for translation on the guide wire proximal of the distal end of the guidewire is disclosed in Irish Application No. 97 0789 (*e.g.*, Fig. 18) and Exhibit 1. The polyimide tube support on which the balloon filter is mounted is disposed for translation on the guidewire proximal of the distal end, and in combination with the stepped guidewire, this tubular support is a capture ring that limits distal translation of the filter element beyond the distal stop of the stepped guidewire.

E. Prior Conception of Count 2 by Applicants

Pursuant to 37 C.F.R. §41.202(a)(4), Applicants will prevail on priority because Applicants were first to conceive the subject matter of proposed Count 2, on a date prior to Broome's parent application filing date (March 5, 1998), and were continuously diligent from a date prior to March 5, 1998 until their constructive reduction to practice of Count 2 by Irish Patent Application No. 98 0267, which was filed on April 8, 1998.

For the reasons set forth above, Broome's parent Application Ser. No. 09/035,740, filed on March 5, 1998, does not describe an anticipation of the subject matter of the proposed counts in compliance with §112, first paragraph, and therefore does not constitute an earlier constructive reduction to practice of the subject matter of the proposed counts under 37 C.F.R. §41.201. Even if Broome's parent application disclosed an anticipation of the subject matter of Count 2, which it does not, Applicants are *prima facie* entitled to priority of invention based on their earlier conception, coupled by diligence to their constructive reduction to practice in Irish Application No. 98 0267. For the reasons set forth above, Broome is not entitled to the filing date of Broome's grandparent application Ser. No. 08/943,358, filed October 3, 1997 (U.S. Patent 6,001,118).

Count 2 differs from Count 1 because (1) Count 2 does not recite a "capture ring;" (2) Count 2 includes the additional limitation that the filter element comprises "a plurality of self-

expanding struts having a filter sac affixed thereto;" (3) Count 2 includes the step of deploying the filter "so that the struts and filter sac expand" to engage a wall of the vessel, the filter "sac" filtering emboli out of blood; and (4) Count 2 recites the step of "retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element."

F. Conception of Filter Element and Method Steps

Prior to March 5, 1998, the applicants conceived of an embodiment of their invention meeting each limitation of proposed Count 2, as demonstrated by the Declaration of Paul Gilson, Eamon Brady, Padraig Maher, David Vale, and Chas Taylor ("Gilson *et al.* Declaration"), ¶¶55-78; and corroborated by the Declaration of Mairsil Claffey ("Claffey Declaration"), ¶¶55-68; and the Declaration of John O'Shaughnessy ("O'Shaughnessy Declaration), ¶¶47-60.

Applicants' prior conception of the following limitations of Count 2 is disclosed and corroborated by their Irish Application No. 97 0789, filed on November 7, 1997:

Disclosure of Irish Application No. 97 0789
Irish Application No. 97 0789 discloses a filter element that provides a pathway for blood and has means for capturing and retaining undesired embolic material released during a surgical procedure (page 11, lines 19-24). IE '789 discloses a device that is used in an over the wire transcatheter configuration, in which the clinician will cross the lesion with a steerable guidewire (page 12, lines 3-5). IE '789 discloses a device that consists of a filter attached to a shaft that can run over the primary crossing guidewire (page 12, lines 11-13); the shaft is disposed for translation on the guide wire proximal of the distal end of the guidewire, for example, substrate shaft 33 in Figs. 11-15 and 18 which is threaded over a guidewire (page 16, lines 6-8). Fig. 18 of IE '789 discloses a filter element having a plurality of Nitinol shape-memory struts, formed to remember an open shape, having a balloon filter affixed to the support (page 18, lines 9-14); the membrane filter fabric may be bonded to the supporting spoke framework (page 15, lines 25-31) or attached over the Nitinol

frame (page 17, lines 6-7).

In accordance with IE '789, the clinician will cross the lesion with a steerable guidewire, and the filter is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 12, lines 4-8).

In accordance with IE '789, the self-expanding filter of Fig. 18 is deployed in the vessel and will capture emboli (page 12, lines 8-11); the expanded filter element will occlude the vessel except for the path or paths provided through the filter (page 12, lines 21-24).

In accordance with IE '789, the deployed filter will capture emboli that are generated or dislodged during balloon inflation and stent placement, which are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 12, lines 8-11; page 19, lines 10-17; claims 23, 24).

In accordance with IE '789, because the shaft or hollow support element (page 12, lines 14-18) on which the filter is mounted is not fixed to the guidewire (page 12, lines 11-13), rotation or distal translation of the guidewire relative to the filter element does not displace the filter element. The guidewire moves independently from the filter: it is first steered across the lesion, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). During retrieval, the filter can be withdrawn either with the guidewire or over it (page 16, lines 23-25). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the filter support shaft thus does not displace the filter element.

(Gilson *et al.* Declaration, ¶57; Claffey Declaration, ¶56).

Prior to March 5, 1998, the inventors conceived of an embodiment shown in Exhibit 1, which is a page from the notebook of inventor David Vale that was made prior to March 5, 1998. (Gilson *et al.* Declaration, ¶58, Exhibit 1). Exhibit 1 shows an apparatus which the inventors conceived, that is used in the method of Count 1. Their conception is corroborated both by Irish Application No. 97 0789, and by the Claffey Declaration, ¶58, Exhibit 1 and the O'Shaughnessy Declaration, ¶48.

Exhibit 1 corroborates their conception of the following limitations of Count 2 (Gilson *et al.* Declaration, ¶58; Claffey Declaration, ¶58; O'Shaughnessy Declaration, ¶48):

Neurogard Details and Dims.
The CHRONOFLEX balloon filter is used in the method disclosed in Irish Application No. 97 0789, as shown in Fig. 18. Guidewire having a maximum shaft outer diameter (O.D.) of 0.014". The balloon filter is disposed on a polyimide tube having an inner diameter (I.D.) of 0.0145", and is thus disposed for translation on the guide wire proximal to the distal end of the guide wire. Self-expanding Nitinol shape-memory struts support the filter sac, shown with large proximal holes and small distal holes, in expanded configuration. Exhibit 1 illustrates the filter polyimide tube support and guidewire extending through a delivery catheter that is transluminally inserted into a vessel, as described in Irish Application No. 97 0789. The self-expanding CHRONOFLEX filter is shown in deployed configuration, as described in Irish Application No. 97 0789, to engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed. Treatment devices such as a balloon catheter or a stent balloon catheter are treatment devices which are inserted into a vessel to treat a portion of the vessel, and in the device shown in Exhibit 1, they are advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789. Because Exhibit 1 describes the inner lumen of the polyimide tube as having a diameter of 0.0145", and the guidewire has a maximum shaft outer diameter of 0.014", Exhibit 1 discloses that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element.

G. Conception and Corroboration of a Guidewire Having "A Distal Stop"

Prior to March 5, 1998, the applicants conceived of a guidewire having a distal stop located at the distal end of the guidewire; a filter element disposed for translation on the

guidewire proximal to the distal stop; and the method step of retracting the guide wire in a proximal direction to cause the distal stop to abut against the polyimide tube support of the filter element. (Gilson *et al.* Declaration, ¶59; Claffey Declaration, ¶¶72-73).

Prior to March 5, 1998, the applicants conceived of a dual-diameter or "stepped" guidewire with a distal end region having a diameter greater than the proximal diameter, which permits the filter element to translate distally and rotate on the guidewire proximal of the thicker distal end, but prevents translation of the filter distal to the thicker distal end, and thus is a stop within the scope of Count 2. (Gilson *et al.* Declaration, ¶68; Claffey Declaration, ¶¶43, 65).

In the applicants' conception of the filter element shown in Exhibit 1, the polyimide tube on which the balloon filter is mounted is designed to rotate and distally translate on the guidewire, because the guidewire has a smaller diameter (0.014″) than the inner lumen of the polyimide tube (0.0145″). (Gilson *et al.* Declaration, ¶61; Claffey Declaration, ¶58). Prior to March 5, 1998, the inventors realized that the small clearance between the guidewire and the polyimide tube caused undesirable friction between the guidewire and the tube. (Gilson *et al.* Declaration, ¶62; Claffey Declaration, ¶59).

In a conference call design review meeting prior to March 5, 1998, Chas Taylor, who is one of the inventors, referred to a solution to this problem by using a custom guidewire, having a thinner proximal portion on which the filter element polyimide tube support is mounted. He referred to using a stepped guidewire having a proximal diameter of 0.012″ and a distal end diameter of 0.018″. (Gilson *et al.* Declaration, ¶69; Claffey Declaration, ¶46). This conception is corroborated by an email describing the meeting, having a date before March 5, 1998, which was attended by inventors Chas Taylor, Padraig Maher, David Vale and Eamon Brady, and also by John O'Shaughnessy. (Gilson *et al.* Declaration, ¶70; Claffey Declaration, ¶47; O'Shaughnessy Declaration, ¶36 (Exhibit 3). The email was sent before March 5, 1998, to Susan Eighan and Mairsil Claffey.

Prior to March 5, 1998, the inventors appreciated that a guidewire, having a distal end portion with a diameter greater than the inner diameter of the polyimide tube (0.0145″) would serve as a distal stop, which would limit distal translation of the filter on the guidewire. (Gilson *et al.* Declaration, ¶71; Claffey Declaration, ¶48).

Prior to March 5, 1998, the inventors decided that the optimal stepped guidewire configuration for use with a polyimide tube filter support having an inner diameter of 0.0145″ was a custom guidewire having a proximal diameter of 0.013″, which would permit rotation and distal translation of the filter on the proximal portion of the guidewire, and a distal end diameter of 0.016″, which would act as a distal stop. (Gilson *et al.* Declaration, ¶51; Claffey Declaration, ¶50).

Their conception is corroborated by an order for the custom stepped 0.013″/0.016″ guidewire, which was placed with a guidewire manufacturer, Lake Region Manufacturing Co., prior to March 5, 1998. This order is confirmed by a facsimile from Tom Kleist of Lake Region, dated prior to March 5, 1998, and an invoice from Lake Region, showing that the custom stepped 0.013″/0.016″ guidewire was shipped to MedNova and received prior to March 5, 1998 (Gilson *et al.* Declaration, ¶52; Claffey Declaration, ¶51; Exhibit 7).

H. Conception and Corroboration of Retracting the Guide Wire in a Proximal Direction to Cause the Distal Stop to Abut against the Filter Element.

The inventors' appreciation of the distal stop function of the stepped guidewire is further corroborated by a memorandum describing a meeting of inventor Chas Taylor with Peter Gaines that took place prior to March 5, 1998 (Gilson *et al.* Declaration, ¶49; O'Shaughnessy Declaration, ¶38; Exhibit 5). This document describes a question from vascular radiologist, Peter Gaines, asking how to remove the guidewire if the tip of the guidewire needs to be reformed, to permit better steering of the guidewire in the vessel if there is any difficulty in passing the lesion

after the guidewire and filter are inserted in the vessel. The document states that because of the stepped guidewire configuration, it cannot be removed from the polyimide support of the filter element. Chas Taylor indicated that the best solution was to remove both the filter and guidewire from the vessel, to reform the guidewire outside the vessel, and to transluminally reinsert both the guide wire and the filter into the vessel through the guiding catheter. (Gilson *et al.* Declaration, ¶49; O'Shaughnessy Declaration, ¶38). The inventors clearly appreciated that the stepped guidewire is a distal stop, because it cannot be withdrawn proximally through the polyimide support of the filter element. (Gilson *et al.* Declaration, ¶49; O'Shaughnessy Declaration, ¶38; Claffey Declaration, ¶49).

Prior to March 5, 1998, the inventors also appreciated that this stepped guidewire configuration providing a distal stop permits the guidewire to be used to withdraw the expanded filter into a retrieval catheter, by retracting the distal stop of the guidewire to abut the end of the polyimide tube support, and pulling the guide wire proximally to retract the filter element into a retrieval catheter. (Gilson *et al.* Declaration, ¶76; Claffey Declaration, ¶66). The inventors thus appreciated that retracting the guide wire in a proximal direction causes the distal stop to abut against the filter element, when the guidewire is pulled to retract the filter element against a retrieval catheter. (Gilson *et al.* Declaration, ¶88; Claffey Declaration, ¶67).

Prior to March 5, 1998, the inventors and co-workers at MedNova constructed an embodiment of a filter device and system as shown in Exhibit 90 which is a photograph of a prototype "NeuroShield Mark 1" embolic filter protection system that was constructed prior to March 5, 1998. (Gilson *et al.* Declaration, ¶77; Claffey Declaration, ¶52; Exhibit 90). Exhibit 90 is a photograph of the prototype apparatus that is designed to be used in the method of Irish Application No. 97 0789 and Count 2. (Gilson *et al.* Declaration, ¶78; Claffey Declaration, ¶68).

This prototype apparatus corroborates their invention of the following limitations of Count 2 (Gilson *et al.* Declaration, ¶78; Claffey Declaration, ¶68):

NeuroShield Mark 1 Prototype (Exhibit 90)
The filter system is used in the method disclosed in Irish Application No. 97 0789, where a representative filter is shown, *e.g.*, in Fig. 18. The balloon filter shown in Exhibit 90 is mounted on a polyimide tube support having an inner diameter of 0.0145", and the filter may be disposed for translation on a guidewire proximal of the distal stop. The polyimide tube support would prevent the filter from translating distal of the guidewire stop. The balloon filter shown in Exhibit 90 has a number of self-expanding Nitinol shape-memory struts supporting the expanded filter sac, which is attached to the Nitinol support. The balloon filter is shown in Exhibit 90 in its deployed configuration, as described in Irish Application No. 97 0789, as it would engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed. Treatment devices such as a balloon catheter or a stent balloon catheter are treatment devices which would be inserted into a vessel to treat a portion of the vessel, and in the device shown in Exhibit 90, they are advanced along a guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789. The inner lumen of the polyimide tube filter support shown in Exhibit 90 has a diameter of 0.0145", and the proximal region of a guidewire for use therewith used with the filter support has an outer diameter of 0.013". Exhibit 90 thus confirms that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element. As shown in Exhibit 90, a guidewire can be translated through the filter polyimide tube support without displacing the filter element. The guidewire can also be rotated in the filter polyimide tube support without displacing the filter element. In order to retrieve the filter, a guidewire is retracted to cause the distal stop to abut against the filter element. The prototype filter system includes a wire lock device, which is used to hold the guidewire in place while the retrieval catheter is pushed over the filter, with the distal stop abutting against the filter element.

Based on the above testimony and documents, the applicants have established a corroborated conception of each and every limitation of proposed Count 2, prior to March 5, 1998.

I. The Applicants' Diligence

In order to establish a *prima facie* showing of prior invention before Broome's March 5, 1998, parent application filing date, the applicants are required to show that they were reasonably diligent in attempting to reduce their conception to practice, commencing on a date that is just prior to March 5, 1998, and that their diligence extended until the applicants' constructive reduction to practice by filing their Irish Application No. 98 0267, on April 8, 1998, *i.e.*, a period of just over one month.

Counts 1 and 2 relate to a method of filtering emboli from blood which includes various steps, including transluminally inserting the guide wire and filter element into a vessel, deploying the filter element in the vessel, filtering emboli out of the blood flowing through the vessel, and advancing a treatment device along the guidewire to treat a portion of the vessel proximal to the location of the filter element. Applicants' efforts to reduce these method steps to practice included preparing various components of the filter element and filter system required to perform tests of the method in a vessel.

1. Dr. Roubin's Tests of Prototype Systems in March and April 1998

During the period from just prior to March 5, 1998 until April 8, 1998, the inventors and their colleagues at MedNova in Ireland were intensely involved in preparing for tests of their filter system in New York, which were conducted at Montefiore Hospital in the Bronx on March 14, 1998 and again on April 5, 1998. Two of the inventors, Paul Gilson and Chas Taylor, attended these tests, which were performed by Dr. Gary Roubin, who is an interventional cardiologist and surgeon. (Gilson *et al.* Declaration, ¶¶87, 96-106; Roubin Declaration, ¶¶20, 31-44).

Chas Taylor contacted Dr. Roubin in January 1998, to arrange for testing of MedNova's prototype NeuroShield embolic filter system. (Gilson *et al.* Declaration, ¶81; Roubin Declaration, ¶16). The March 14, 1998 tests are described in Dr. Roubin's declaration (¶¶17-49), and fluoroscopic images of this test are attached to Dr. Roubin's declaration as Exhibit 91 (Roubin Declaration, ¶19). The April 5, 1998 tests conducted by Dr. Roubin are described in his declaration at paragraphs 64-71.

These tests were performed using a simulated artery containing a surgically explanted human carotid artery plaque (Roubin Declaration, ¶¶11-13, 21). The model has significant advantages over animal tests or human trials in determining whether an embolic filter device successfully removes emboli from the bloodstream, because it is possible to evaluate emboli that escape past the filter, as well as emboli captured by the filter. (Roubin Declaration, ¶12). In the model, blood flow through the vessel and filter are simulated using saline solution pumped through the Teflon vessel. (Roubin Declaration, ¶11).

In the tests conducted by Dr. Roubin on March 14, 1998, the embolic filter device comprised a self-expanding filter sac, as shown in Exhibit 90. (Gilson *et al.* Declaration, ¶85; Roubin Declaration, ¶23; Claffey Declaration, ¶77). The structure of this filter is also schematically shown in Exhibit 65 (second page, top figure)

The structure of this filter is visible in the fluoroscopic image, including the Nitinol struts which expand when the filter is released from the delivery catheter, and the platinum end marker (Roubin Declaration, ¶27; Exhibit 91, "2:55 Nitinol filter frame deployed in vessel").

The embolic filter element included a filter sac attached to a Nitinol support having a number of self-expanding struts, and the Nitinol framework was attached to a polyimide tube

support, having an inner diameter of 0.0145". (Roubin Declaration, ¶24; Gilson *et al.* Declaration, ¶¶89-90; Claffey Declaration, ¶¶74-75).

The "NeuroShield" device which Dr. Roubin tested on March 14, 1998, utilized a stepped guidewire having a distal stop. (Roubin Declaration, ¶22; Gilson *et al.* Declaration, ¶¶89-90; Claffey Declaration, ¶74). The distal end of the guidewire had a diameter (*i.e.*, 0.016") that was greater than the diameter of the polyimide tube filter support, and provided a stop which prevented distal translation of the filter element beyond the guidewire distal stop. (Roubin Declaration, ¶22; Gilson *et al.* Declaration, ¶¶89-90; Claffey Declaration, ¶74). The region of the guidewire proximal to the distal stop had a diameter (*i.e.*, 0.013") that was smaller than the lumen of the polyimide tube supporting the filter. (Roubin Declaration, ¶22; Gilson *et al.* Declaration, ¶¶89-90; Claffey Declaration, ¶74). It was therefore possible to rotate and translate the guidewire relative to the filter and its polyimide support. (Roubin Declaration, ¶22; Gilson *et al.* Declaration, ¶102; Claffey Declaration, ¶81).

In the tests conducted by Dr. Roubin, it was necessary to compress the filter using a loading device, and to insert the compressed filter and guidewire into a delivery catheter. (Roubin Declaration, ¶29; Gilson *et al.* Declaration, ¶95). Dr. Roubin then transluminally inserted the delivery catheter, including the guidewire and compressed filter, into the simulated vessel of the model. (Roubin Declaration, ¶30; Gilson *et al.* Declaration, ¶96). Dr. Roubin successfully crossed the human plaque narrowing the vessel with the guidewire, and during this procedure, the guidewire rotated and translated distally relative to the filter element (Roubin Declaration, ¶32; Gilson *et al.* Declaration, ¶97). The delivery catheter was used to transluminally insert the filter and guidewire to a position distal of the plaque in the vessel. (Roubin Declaration, ¶33; Gilson *et al.* Declaration, ¶98).

The filter element was then deployed in the vessel distal of the lesion, so that the struts and filter sac thereof expanded to engage a wall of the vessel. (Roubin Declaration, ¶34; Gilson

et al. Declaration, ¶99). Dr. Roubin advanced a stent system (*i.e.*, a treatment device) along the guidewire to a position proximal to the location of the deployed filter, and retracted the sheath so that the stent was expanded over the lesion.

During these treatment steps, emboli were dislodged from the human plaque, and were successfully captured in the filter. (Roubin Declaration, ¶¶36, 40 and 44; Gilson *et al.* Declaration, ¶¶101, 106). The tests confirmed that the filter filtered emboli out of the saline solution pumped through the simulated artery. (Roubin Declaration, ¶45; Gilson *et al.* Declaration, ¶107).

Dr. Roubin advanced a retrieval catheter along the guidewire to the distal end of the stent, proximal of the expanded filter. (Roubin Declaration, ¶41; Gilson *et al.* Declaration, ¶104). The guidewire was retracted to cause the distal stop of the guidewire to abut against the polyimide filter support. (Roubin Declaration, ¶42; Gilson *et al.* Declaration, ¶105). Dr. Roubin then advanced the retrieval catheter over the filter to collapse the filter and withdraw it into the retrieval catheter. (Roubin Declaration, ¶43; Gilson *et al.* Declaration, ¶105). During this procedure, the guidewire was rotated and distally translated relative to the filter element, both before deployment and after expanding the filter in the vessel. (Roubin Declaration, ¶47; Gilson *et al.* Declaration, ¶109). Rotation and distal translation of the guidewire did not displace the expanded filter element deployed in the vessel. (Roubin Declaration, ¶47; Gilson *et al.* Declaration, ¶109).

The results of the March 14, 1998 tests conducted by Dr. Roubin are summarized in a memorandum dated on March 18, 1998, by Paul Gilson. (Gilson *et al.* Declaration, ¶112; Claffey Declaration, ¶80; Exhibit 37). This memorandum was disclosed to the MedNova design team on or shortly after March 18, 1998, and it accurately describes the tests performed by Dr. Roubin (Roubin Declaration, ¶50; Gilson *et al.* Declaration, ¶112). Exhibit 37 confirms that the 0.013″/0.016″ stepped guidewire was used in the March 14, 1998 test, with a 6mm NeuroShield

filter, and further states as follows: The wire moved distal/proximal in the filter shaft. The filter deployed satisfactorily in the simulated vessel, and the Nitinol element opened and was visible fluoroscopically. The dilation balloon was loaded and the lesion angioplastied, and there was visual evidence of embolic material being released. The wall stent was deployed and visibly released debris, after which the stent delivery system was removed. The retrieval system was then loaded and advanced into the stent at its distal end, and the filter and wire were then pulled back into the catheter and it was removed. The filter was removed and cut open, and a number of large embolic particles were visible. The system was successfully deployed in the simulated vessel, and performed its function of filtering emboli from saline solution flowing through the vessel.

As a result of the information obtained during the March 14, 1998 tests in New York, the applicants and their colleagues designed a version of the NueroShield embolic filter which was intended to provide better movement of the guidewire. (Gilson *et al.* Declaration, ¶113; Claffey Declaration, ¶81; Roubin Declaration, ¶52). A prototype of the NeuroShield embolic filter was prepared for testing by Dr. Roubin on April 5, 1998. (Roubin Declaration, ¶53; Gilson *et al.* Declaration, ¶¶113-114; Claffey Declaration, ¶82). During the period from March 14, 1998, until April 5, 1998, the inventors and co-workers from MedNova worked intensely and continuously to design and produce the modified embolic filter system. (Gilson *et al.* Declaration, ¶113-116; Claffey Declaration, ¶81-84). It was a major undertaking to redesign the filter element, and to produce additional modified prototype devices, for the second test of the filter system, within three weeks. (Gilson *et al.* Declaration, ¶116; Claffey Declaration, ¶84).

On March 24, 1998, Paul Gilson disclosed the modified version of the "NeuroShield" embolic filter to Dr. Roubin in a facsimile. (Roubin Declaration, ¶53; Gilson *et al.* Declaration, ¶114; Claffey Declaration, ¶82).

In his March 24, 1998 facsimile, Paul Gilson described MedNova's changes to the "NeuroShield" embolic filter, which included mounting the filter on a short polyimide tube support to which the Nitinol filter support was bonded. This configuration allowed the filter assembly to freely move between pre-determined stops on the guide wire, and thus the wire was free to torque and to have limited movement longitudinally (Roubin Declaration, ¶54; Gilson *et al.* Declaration, ¶115; Exhibit 60, page 3; Claffey Declaration, ¶83).

The modified NeuroShield filter and guidewire which Dr. Roubin tested on April 5, 1998, are accurately described in Exhibit 88. (Roubin Declaration, ¶63, Exhibit 88; Gilson *et al.* Declaration, ¶122; Claffey Declaration, ¶89).

The "NeuroShield" device tested on April 5, 1998 utilized a stepped (0.013″/0.016″) guidewire having a distal stop. (Roubin Declaration, ¶59; Gilson *et al.* Declaration, ¶120; Claffey Declaration, ¶87). In the "NeuroShield" device, the stepped guidewire was preloaded through a balloon filter element having a filter sac which was affixed to a Nitinol support having a number of self-expanding struts. (Roubin Declaration, ¶60; Gilson *et al.* Declaration, ¶121; Claffey Declaration, ¶88). In the "NeuroShield" device, the Nitinol structure was attached to a short (about 40 mm) polyimide tube support disposed on the proximal portion of the guidewire (having a diameter of 0.013″), between the distal stop and a proximal stop, as shown in Exhibit 60, page 3, and Exhibits 81 and 88). (Roubin Declaration, ¶61; Gilson *et al.* Declaration, ¶122; Claffey Declaration, ¶89). Because the short polyimide tube had a lumen with an inner diameter smaller than the diameter of the distal end of the stepped guidewire (0.016″), the distal end of the guidewire would not pass through the polyimide tube and provided a distal stop on the guidewire. The filter element was disposed for translation and rotation on the stepped guidewire proximal of the distal stop. (Roubin Declaration, ¶61; Gilson *et al.* Declaration, ¶122; Claffey Declaration, ¶89). The short polyimide tube (about 40 mm) floated on the guidewire between the distal stop and the proximal stop, and the filter element was thus capable of rotation and

distal translation with respect to the guidewire. (Roubin Declaration, ¶62; Gilson *et al.* Declaration, ¶123; Claffey Declaration, ¶90).

The second test of the inventors' embolic filter system was conducted in New York by Dr. Roubin on April 5, 1998. (Roubin Declaration, ¶56; Gilson *et al.* Declaration, ¶117; Claffey Declaration, ¶85). Paul Gilson and Chas Taylor attended this test (Roubin Declaration, ¶57; Gilson *et al.* Declaration, ¶118; Claffey Declaration, ¶86). This test was performed using the model with a simulated artery containing a surgically excised human carotid artery plaque. (Roubin Declaration, ¶58, Gilson *et al.* Declaration, ¶119).

During the April 5, 1998 test, the guidewire and compressed filter element were first inserted into a delivery catheter. (Roubin Declaration, ¶64; Gilson *et al.* Declaration, ¶126). Dr. Roubin then transluminally inserted the delivery catheter, including the guidewire and filter, into the simulated vessel. (Roubin Declaration, ¶65; Gilson *et al.* Declaration, ¶126). He successfully crossed the plaque narrowing the vessel with the delivery catheter, to a position distal of the plaque, and then deployed the filter element so that the struts and filter sac thereof expanded to engage a wall of the vessel. (Roubin Declaration, ¶¶66-67; Gilson *et al.* Declaration, ¶¶127-128).

Dr. Roubin advanced a balloon dilation catheter (i.e., a treatment device) along the guidewire to a position proximal to the location of the deployed filter, and expanded the balloon to dilate the plaque (i.e., treat a portion of the vessel). (Roubin Declaration, ¶68; Gilson *et al.* Declaration, ¶129). He retracted the balloon catheter, and advanced a stent along the guidewire to a position over the plaque, where the stent was expanded. (Roubin Declaration, ¶69; Gilson *et al.* Declaration, ¶131). During these steps, emboli were dislodged from the plaque, and were successfully captured in the filter. (Roubin Declaration, ¶70; Gilson *et al.* Declaration, ¶131).

Dr. Roubin then advanced a retrieval catheter along the guidewire to a position distal of the stent and proximal of the expanded filter. (Roubin Declaration, ¶71; Gilson *et al.* Declaration, ¶132). He retracted the guide wire in a proximal direction to cause the distal stop of the guidewire to abut against the polyimide filter support, and withdrew the filter into the pod of the retrieval catheter. (Roubin Declaration, ¶¶72-73; Gilson *et al.* Declaration, ¶¶133-134).

Dr. Roubin then removed the retrieval catheter containing the filter from the simulated artery, and removed the filter from the retrieval catheter and cut it open. (Roubin Declaration, ¶¶73-74; Gilson *et al.* Declaration, ¶¶134-135). A number of large embolic particles were visible in the opened filter. (Roubin Declaration, ¶74; Gilson *et al.* Declaration, ¶135). Dr. Roubin thus confirmed that the filter filtered emboli out of the saline solution pumped through the vessel. (Roubin Declaration, ¶75; Gilson *et al.* Declaration, ¶136).

Dr. Roubin found that the system successfully crossed the lesion, deployed the filter, captured embolic material and was retrieved. (Roubin Declaration, ¶76; Gilson *et al.* Declaration, ¶136).

In the April 5, 1998 tests, rotation and distal translation of the guide wire relative to the deployed filter were maintained and improved in comparison with the earlier version of the "NeuroShield" device tested on March 14, 1998. (Roubin Declaration, ¶77; Gilson *et al.* Declaration, ¶137). During the procedure performed on April 5, 1998, rotation and distal translation of the guidewire relative to the filter element did not displace the filter element. (Roubin Declaration, ¶78). During the procedure performed on April 5, 1998, wire movement and interface, as well as handling of the filter during both preparation and use, in comparison with the earlier version of the "NeuroShield" device which Dr. Roubin tested on March 14, 1998. (Roubin Declaration, ¶79).

At the time Dr. Roubin conducted these tests of the MedNova prototype embolic filter systems, he was Chief of Endovascular Services at Lenox Hill Hospital in New York, New York. (Roubin Declaration, ¶3). Dr. Roubin has performed approximately 2000 carotid artery angioplasty/stent procedures. (Roubin Declaration, ¶4). Based on his experience in endovascular surgery, Dr. Roubin concluded that the tests of the NeuroShield filter which he performed on March 14, 1998 and April 5, 1998, satisfactorily demonstrated that the embolic filter device and system would successfully perform the function of removing emboli from blood flowing through a vessel during carotid artery angioplasty procedures in a human patient. (Roubin Declaration, ¶80). In his opinion, the test results of the NeuroShield filter which he performed on March 14, 1998 and April 5, 1998, are sufficiently correlated with the conditions found in actual angioplasty procedures on human patients, to establish that the NeuroShield embolic filter would perform its intended function of filtering emboli from the blood of a patient undergoing carotid angioplasty procedures, in a human artery. (Roubin Declaration, ¶80).

2. Applicants' Preparation for the New York Tests

In order to prepare for the two tests conducted by Dr. Roubin in New York on March 14, 1998 and April 5, 1998, the inventors and colleagues working at their direction were intensely busy throughout the period from at least late February 1998 until April 5, 1998. (Gilson Declaration, ¶141; Claffey Declaration, ¶97). Based on the two tests conducted by Dr. Roubin, the inventors and their colleagues at MedNova continued their efforts to modify, improve, and perfect the filter element from April 5, 1998 until April 8, 1998, when their Irish Application No. 98 0267 was filed (Gilson *et al.* Declaration, ¶138; Claffey Declaration, ¶92).

Their efforts to reduce to practice the inventions defined by Count 1 and Count 2 are described in detail in the attached Gilson *et al.* Declaration, ¶¶139-290, and Claffey Declaration, ¶¶92-241. These continuous efforts were directed at improving the parts of the filter element, as well as the components such as the delivery catheter used to transluminally insert the guidewire and filter element into a vessel. (Gilson Declaration, ¶139; Claffey Declaration, ¶93).

These efforts are corroborated by numerous documents, including detailed filter development Project Team Meeting Reviews, summarizing the activities of each team member directed toward an actual reduction to practice in the preceding and following week. (Gilson Declaration, ¶¶140-141; Claffey Declaration, ¶94). The Project Team Meeting Reviews demonstrate that the inventors and their colleagues were working intensely and continuously to produce a filter and system that would be shown to be practically useful in the tests conducted by Dr. Roubin, during the critical period from a date just prior to March 5, 1998, until April 8, 1998. (Gilson Declaration, ¶141; Claffey Declaration, ¶97). These Project Team Meeting Reviews are included as the following exhibits to the Gilson *et al.* Declaration, and Claffey Declaration:

February 25, 1998:	Exhibit 8
March 5, 1998:	Exhibit 22
March 11, 1998:	Exhibit 33
March 18, 1998:	Exhibit 48
March 24, 1998:	Exhibit 38
April 1, 1998:	Exhibit 74
April 2, 1998:	Exhibit 77
April 6, 1998:	Exhibit 83

During the period from February 1998 until April 8, 1998, inventor Paul Gilson was employed by MedNova as Executive Director and Chief Scientific Officer. He was responsible for Operations, Research and Development, Regulatory Affairs and Quality Control. (Gilson *et al.* Declaration, ¶11; Claffey Declaration, ¶6). During the period from February 1998 until April 8, 1998, Paul Gilson arranged for Dr. Roubin to conduct the tests; coordinated the tests in New York on March 14, 1998 and April 5, 1998; traveled to New York to attend these tests; evaluated the results of the tests; modified and improved the filter to improve movement of the guidewire

relative to the filter; and worked with Dr. Roubin in evaluating the design changes proposed by the inventors. (Gilson *et al.* Declaration, ¶142; Claffey Declaration, ¶98).

During this period, Eamon Brady was engaged by MedNova as Research and Development Manager. Eamon Brady was responsible for MedNova's embolic filter protection device development project. . (Gilson *et al.* Declaration, ¶12; Claffey Declaration, ¶7;O'Shaughnessy Declaration ¶7).

The Project Team Meeting Reviews confirm that during the critical period, Susan Eighan, who was a Manufacturing Engineer, worked to make final packs or packages of devices for the tests conducted by Dr. Roubin (Exh. 22, 33), as well as working on the core removal process for making the filter balloon sacs (Exh. 33), making and improving Nitinol supports (Exh. 33, 77, 83), building filter samples (Exh. 48) and manufacturing the filter assembly (Exh. 38, page 2). (Gilson *et al.* Declaration, ¶153; Claffey Declaration, ¶99).

During this period, Steven Horan, who was a Research and Development Engineer, worked principally on the balloon filter sac, including narrowing the balloon wall thickness distribution, updating the dip and core assembly procedures used to make the balloons, and conducting tests of the balloons (Exh. 8, 22); building 36 balloons for the tests conducted by Dr. Roubin (Exh. 22, 33); analyzing balloon data and evaluating balloon strengths, ordering cores for making the balloons, and dipping balloons for UV trials (Exh. 33, 48); prototyping alternative balloons for the April 5, 1998 trials in New York (Exh. 38, page 1), including tapered filter or stepped filter or grooved filter designs to improve filter performance in undersized vessels (Exh. 74); making and testing about 35 prototype balloons for the April 5, 1998 trials (Exh. 77); and evaluating and testing a series of filter geometries and sizes (Exh. 83). (Gilson *et al.* Declaration, ¶144; Claffey Declaration, ¶100).

Inventor Padraig Maher, who was a Research Engineer, tested Nitinol supports, provided samples of the Nitinol supports to a laser machining company, and tested the loading force required to load the filter element into a delivery catheter and tested the maneuverability of the delivery catheter (Exh. 8, 22, 33); defined a balloon wrap method (Exh. 22, 33); worked with Chas Taylor to increase the number of distal holes in the balloon filter (Exh. 38, page 2); ordered thicker polyimide tube for the filter support, and built prototypes using the new polyimide tube (Exh. 74, 77, 83); increased the size of the proximal filter holes (Exh. 83); and designed and built "olives" to improve the transition from the delivery catheter to the filter element (Exh. 74, 77, 83). (Gilson *et al.* Declaration, ¶145; Claffey Declaration, ¶101).

During the critical period, Keith Ryan, a technician, worked with David Vale on developing the delivery catheter pod used to transluminally insert the filter and guidewire past the plaque, and tested pod tensile strengths (Exh. 8); worked on the rig used to test the PTFE pod attachment (Exh. 22); built 10 loading mechanisms for use in the trials, which were used to load the filter element into the delivery catheter (Exh. 33); tested additional loading mechanisms (Exh. 77, 83); and worked on the wall thickness and diameter of the Teflon pod of the delivery catheter (Exh 74, 77); and modified the loading mechanism transition of the delivery catheter (Exh. 77, 83). (Gilson *et al.* Declaration, ¶¶146; Claffey Declaration, ¶102).

Inventor David Vale, who was Senior Research and Development Engineer, worked on the retrieval catheter specifications (Exh. 22, 33); worked on the delivery catheter (Exh. 38, page 2); modified the filter element design, and worked on the stops for the filter, as well as materials and processes for the stops to the guidewire (Exh. 74, 77); designed, built and evaluated a filter design with floating distal bonds (Exh. 83); and worked on improving the smoothness of guidewire transitions and improving guidewire stiffness (Exh. 83, page 2). (Gilson *et al.* Declaration, ¶147; Claffey Declaration, ¶103).

The activities of the inventors and their colleagues during the critical period, in attempting to reduce to practice their conception of the methods of proposed Counts 1 and 2, are described on a day-to-day basis in the attached Gilson *et al.* Declaration, ¶¶148-290 and Claffey Declaration, ¶¶104-241. Their testimony is further corroborated by Exhibits 8-75 and 77-88, which are described in detail in the Declarations. During the period from February 1998 until April 8, 1998, Mairsil Claffey was Quality Assurance and Regulatory Manager of MedNova, and was familiar with the inventors' work and with the work of other MedNova researchers and engineers in developing the embolic filter system. (Claffey Declaration, ¶¶3-4, 20).

Throughout the critical period from just prior to March 5, 1998, until April 8, 1998, the inventors and their colleagues at MedNova were continuously diligent in attempting to reduce to practice the methods of proposed Count 1 and Count 2.

VI. STATEMENT PURSUANT TO 37 C.F.R. §41.202(a)(5)

Pursuant to 37 C.F.R. §41.202(a)(5), the Applicants provide written description support for each limitation of Claims 44, 48, 49, 53, 65, 67, 68, 85, 92, 93, 96, 97, 98 and 99 as shown in the following table.

Applicants' Claims	Disclosure of Ser. No. 10/058,828
44. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:	Embolic protection device 100 shown in Figs. 40-42 (page 25, lines 6-7), comprising:
a guide wire having a distal region and a stop on the distal region;	A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-8), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17).
a capture ring disposed for translation on the guide wire,	
the stop limiting translation of the capture ring in a distal direction; and	

a self-expanding filter sac connected to the capture ring;	The capture ring is tubular sleeve 104, which is slidably mounted on the guidewire 101, and collapsible filter 105 is mounted on the sleeve 104 (page 25, lines 9-11); the filter sac may be bonded onto the tubing substrate (page 19, lines 32-34). Figs. 40-42: filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111 (page 25, lines 19-20); in use when the filter is positioned in a vessel, the catheter 118 is retracted allowing the support frame 111 to expand inflating the net 110 across the vessel in which the filter is mounted (page 26, lines 12-15).
wherein, when the filter sac is deployed in the vessel, rotation or distal translation of the guide wire relative to the capture ring does not displace the filter sac,	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9, lines 28-30).
but retraction of the guide wire in a proximal direction causes the stop to abut against the capture ring.	Fig. 42: retraction of the guide wire 101 in a proximal direction causes distal stop 107 to abut against tubing substrate 104 (as shown retracted from its position in Fig. 41). At the end of the procedure, a sheath is advanced to the proximal end of the device, and the filter is

	pulled proximally into it (page 20, lines 20-22), by retracting the guidewire, which is the only way to pull the filter shown in Figs. 41 and 42 proximally into the retrieval catheter.
48. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising: a guide wire having a first portion having a first diameter and a distal region having a second diameter greater than the first diameter; and a self-expanding filter element having a capture ring disposed for translation on the first portion, the capture ring having an aperture greater than the first diameter but smaller than the second diameter, wherein rotation or distal translation of the guide wire relative to the capture ring does not displace the filter element.	Embolic protection device 100 shown in Figs. 40-42 (page 25, lines 6-7), comprising: A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-8), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17). The capture ring is tubular sleeve 104, which is slidably mounted on the guidewire 101 and thus has an aperture greater than the guidewire first diameter (page 25, lines 15-17); the outer stop which is formed by spring tip 107 has a diameter which is greater than the aperture of sleeve 104 such that it functions as a stop (page 25, lines 15-17) (as shown in Figs. 41-42). Figs. 40-42: filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111 (page 25, lines 19-20); in use when the filter is positioned in a vessel, the catheter 118 is retracted allowing the support frame 111 to expand inflating the net 110 across the vessel in which the filter is mounted (page 26, lines 12-15). The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters

	(page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9, lines 28-30).
49. The apparatus of claim 48 wherein the filter element comprises an expandable sac.	Figs. 40-42: filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111 (page 25, lines 19-20); in use when the filter is positioned in a vessel, the catheter 118 is retracted allowing the support frame 111 to expand inflating the net 110 across the vessel in which the filter is mounted (page 26, lines 12-15).
53. The apparatus of claim 48 wherein the guide wire further comprises a flange disposed on the distal region having a diameter larger than the diameter of the aperture in the capture ring.	Fig. 41: stopper 106 is a flange disposed on the distal region having a diameter larger than the diameter of the aperture in sleeve 104. In the embodiment disclosed in Fig. 30, guidewire 2 comprises a flange 64 disposed on the distal region, which has a diameter larger than the diameter of the aperture in sleeve 33, which is a capture ring to which the filter element 1 is attached.
65. A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal stop,	Filter 105 shown in Figs. 40-42 is positioned in a vessel, and filters emboli from blood flowing through the net wall (page 26, lines 12-18) using the device 100 comprising: A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-9), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops,

	namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17).
and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	The capture ring is tubular sleeve 104, which is slidably mounted on the guidewire 101, and collapsible filter 105 is mounted on the sleeve 104 (page 26, lines 8-13).
transluminally inserting the guide wire and filter element into a vessel;	Filter 105 is mounted in a collapsed state within a distal end of catheter 118 and delivered to a deployment site in a vessel (page 26, lines 12-13).
deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	When the filter is correctly positioned the catheter 118 is retracted "allowing the support frame to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall; however, the openings or pores in the net are sized so as to retain the embolic material." (page 26, lines 13-18).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	When the filter has been deployed in a blood vessel, the catheter can be removed leaving a bare guidewire proximal to the filter for use with known devices such as balloon catheter and stent devices upstream of the filter (page 27, lines 13-15).
rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move

	axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9, lines 28-30).
67. The method of claim 65 further comprising: providing a delivery sheath; and compressing the filter element to a contracted state to insert the filter element within the delivery sheath.	In use, the filter 105 is mounted in a collapsed state within a distal end of the delivery catheter 118 and delivered to a deployment site (page 26, lines 12-13).
68. The method of claim 65 wherein the filter element comprises an expandable sac, and deploying the filter element comprises expanding the expandable sac so that a perimeter of the expandable sac contacts the wall of the vessel.	When the filter is correctly positioned the catheter 118 is retracted allowing the support frame 111 to expand inflating the net 110 across the vessel in which the filter is mounted (page 26, lines 13-15).

Applicants' Claims	**Disclosure of Ser. No. 10/058,828**
85. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising: a guide wire having a distal stop; a filter element disposed for rotation on a distal region of the guide wire,	Embolic protection device 100 shown in Figs. 40-42, comprising: A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-9). A collapsible filter 105 mounted on a tubular sleeve 104 which is slidably mounted on the distal region of guidewire 101 (page 25, lines 10-13); between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire

	101 (page 25, lines 15-17).
the filter element comprising a self-expanding strut and a filter sac connected to the self-expanding strut; and	The filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111 which is naturally expanded (page 25, lines 19-29) and expands when the delivery catheter is retracted (page 26, lines 13-15); as shown in Fig. 18, collapsible filter support element 50 has a number of foldable arms 51 which collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel (page 20, line 32-page 21, line 3); the membrane filter fabric may be bonded to the supporting spoke framework (page 19, lines 6-11) or attached over the Nitinol frame (page 20, lines 3-8).
the distal stop disposed on the distal region distal to the filter element, the distal stop limiting distal translation of the filter element on the guide wire;	The sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101 (page 25, lines 15-17); collapsible filter 105 is mounted on the sleeve 104 (page 25, lines 10-14).
wherein, when the filter sac is deployed in the vessel, rotation of the guide wire does not displace the filter element.	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of

	the filter (page 9, lines 28-30).
92. A method of filtering emboli from blood flowing through a vessel, the method comprising:	Filter 105 shown in Figs. 40-42 is positioned in a vessel, and filters emboli from blood flowing through the net wall (page 26, lines 12-18), using the device 100 comprising:
providing a guide wire having a distal stop,	A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-9), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17).
and a filter element disposed for translation on the guide wire proximal to the distal stop,	Collapsible filter 105 is mounted on tubular sleeve 104, which is slidably mounted on the guidewire 101 proximal to stop 107 (page 25, lines 10-13); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25).
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	The filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111 which is naturally expanded (page 25, lines 19-29) and expands when the delivery catheter is retracted (page 26, lines 12-15); as shown in Fig. 18, collapsible filter support element 50 has a number of foldable arms 51 which collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel (page 20, line 33 to page 21, line 3); the membrane filter fabric may be bonded to the supporting spoke framework (page 19, lines 6-11) or attached

	over the Nitinol frame (page 20, lines 3-8).
transluminally inserting the guide wire and filter element into a vessel;	Filter 105 is mounted in a collapsed state within a distal end of catheter 118 and delivered to a deployment site in a vessel (page 26, lines 12-13).
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	When the filter is correctly positioned "the catheter 118 is retracted allowing the support frame to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall; however, the openings or pores in the net are sized so as to retain the embolic material." (page 26, lines 13-18).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	When the filter has been deployed in a blood vessel, the catheter can be removed leaving a bare guidewire proximal to the filter for use with known devices such as balloon catheter and stent devices upstream of the filter (page 27, lines 13-15).
rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element.	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9, lines 28-30).

93. A method of filtering emboli from blood flowing through a vessel, the method comprising:	Filter 105 shown in Figs. 40-42 is positioned in a vessel, and filters emboli from blood flowing through the net wall (page 26, lines 12-18), using the device 100 comprising:
providing a guide wire having a distal region including a distal stop,	A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-9), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17).
and a filter element disposed for translation on the guide wire proximal to the distal stop,	Collapsible filter 105 is mounted on tubular sleeve 104, which is slidably mounted on the guidewire 101 proximal to stop 107 (page 25, lines 10-13); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25).
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	The filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111 which is naturally expanded (page 25, lines 19-29) and expands when the delivery catheter is retracted (page 26, lines 12-15); as shown in Fig. 18, collapsible filter support element 50 has a number of foldable arms 51 which collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel (page 20, line 33 to page 21, line 3); the membrane filter fabric may be bonded to the supporting spoke framework (page 19, lines 6-11) or attached over the Nitinol frame (page 20, lines 3-8).

transluminally inserting the guide wire and filter element into a vessel;	Filter 105 is mounted in a collapsed state within a distal end of catheter 118 and delivered to a deployment site in a vessel (page 26, lines 12-13).
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	When the filter is correctly positioned "the catheter 118 is retracted allowing the support frame to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall; however, the openings or pores in the net are sized so as to retain the embolic material." (page 26, lines 13-18).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	When the filter has been deployed in a blood vessel, the catheter can be removed leaving a bare guidewire proximal to the filter for use with known devices such as balloon catheter and stent devices upstream of the filter (page 27, lines 13-15).
rotation or distal translation of the guide wire relative to the filter element imparted by the treatment device not displacing the filter element;	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9, lines 28-30).
further comprising retracting the guide wire in	Fig. 42: retraction of the guide wire 101 in a

a proximal direction to cause the distal stop to abut against the filter element.	proximal direction causes distal stop 107 to abut against tubing substrate 104 (as shown retracted from position in Fig. 41). At the end of the procedure, a sheath is advanced to the proximal end of the device, and the filter is pulled proximally into it (page 20, lines 20-22), by retracting the guidewire, which is the only way to pull the filter shown in Figs. 41 and 42 proximally into the retrieval catheter.
96. The method of claim 92 further comprising: providing a retrieval catheter having a pod; advancing the retrieval catheter over the guide wire until the pod covers a mouth of the filter element; and urging the retrieval catheter against the self-expanding struts of the filter element to cause the filter element to collapse.	 The tip of the catheter which forms a housing or pod for reception of the filter is of an elastic material which can radially expand to accommodate the filter with the captured embolic material. . . . when retrieving the fitter, the catheter tip or pod is sufficiently elastic to accommodate the extra bulk of the filter due to the embolic material (page 26, line 31 to page 27, line 3). After use the catheter is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet end 112 first to close the openings and then gradually collapsing the net against the sleeve 104 as the catheter 118 advances over the filter 105 (page 26, lines 18-22).

97. A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal stop,	Filter 105 shown in Figs. 40-42 is positioned in a vessel, and filters emboli from blood flowing through the net wall (page 26, lines 12-18) using the device 100 comprising: A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-9), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops,

	namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17).
and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	The capture ring is tubular sleeve 104, which is slidably mounted on the guidewire 101, and collapsible filter 105 is mounted on the sleeve 104 (page 26, lines 8-13).
transluminally inserting the guide wire and filter element into a vessel;	Filter 105 is mounted in a collapsed state within a distal end of catheter 118 and delivered to a deployment site in a vessel (page 26, lines 12-13).
deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	When the filter is correctly positioned the catheter 118 is retracted "allowing the support frame to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall; however, the openings or pores in the net are sized so as to retain the embolic material." (page 26, lines 13-18).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	When the filter has been deployed in a blood vessel, the catheter can be removed leaving a bare guidewire proximal to the filter for use with known devices such as balloon catheter and stent devices upstream of the filter (page 27, lines 13-15).
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element.	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move

	axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9, lines 28-30).

98. A method of filtering emboli from blood flowing through a vessel, the method comprising:	Filter 105 shown in Figs. 40-42 is positioned in a vessel, and filters emboli from blood flowing through the net wall (page 26, lines 12-18), using the device 100 comprising:
providing a guide wire having a distal region including a distal stop,	A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-9), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17).
and a filter element disposed for translation on the guide wire proximal to the distal stop,	Collapsible filter 105 is mounted on tubular sleeve 104, which is slidably mounted on the guidewire 101 proximal to stop 107 (page 25, lines 10-13); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25).
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	The filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111 which is naturally expanded (page 25, lines 19-29) and expands when the delivery catheter is retracted (page 26, lines 12-15); as shown in Fig. 18, collapsible filter support element 50 has a number of foldable arms 51 which

	collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel (page 20, line 33 to page 21, line 3); the membrane filter fabric may be bonded to the supporting spoke framework (page 19, lines 6-11) or attached over the Nitinol frame (page 20, lines 3-8).
transluminally inserting the guide wire and filter element into a vessel;	Filter 105 is mounted in a collapsed state within a distal end of catheter 118 and delivered to a deployment site in a vessel (page 26, lines 12-13).
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	When the filter is correctly positioned "the catheter 118 is retracted allowing the support frame to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall; however, the openings or pores in the net are sized so as to retain the embolic material." (page 26, lines 13-18).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	When the filter has been deployed in a blood vessel, the catheter can be removed leaving a bare guidewire proximal to the filter for use with known devices such as balloon catheter and stent devices upstream of the filter (page 27, lines 13-15).
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to

	rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9, lines 28-30).
further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	Fig. 42: retraction of the guide wire 101 in a proximal direction causes distal stop 107 to abut against tubing substrate 104 (as shown retracted from position in Fig. 41). At the end of the procedure, a sheath is advanced to the proximal end of the device, and the filter is pulled proximally into it (page 20, lines 20-22), by retracting the guidewire, which is the only way to pull the filter shown in Figs. 41 and 42 proximally into the retrieval catheter.

99. A method of filtering emboli from blood flowing through a vessel, the method comprising:	Filter 105 shown in Figs. 40-42 is positioned in a vessel, and filters emboli from blood flowing through the net wall (page 26, lines 12-18), using the device 100 comprising:
providing a guide wire having a distal stop,	A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-9), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17).
and a filter element disposed for translation on the guide wire proximal to the distal stop,	Collapsible filter 105 is mounted on tubular sleeve 104, which is slidably mounted on the guidewire 101 proximal to stop 107 (page 25, lines 10-13); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has

	complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25).
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	The filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111 which is naturally expanded (page 25, lines 19-29) and expands when the delivery catheter is retracted (page 26, lines 12-15); as shown in Fig. 18, collapsible filter support element 50 has a number of foldable arms 51 which collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel (page 20, line 33 to page 21, line 3); the membrane filter fabric may be bonded to the supporting spoke framework (page 19, lines 6-11) or attached over the Nitinol frame (page 20, lines 3-8).
transluminally inserting the guide wire and filter element into a vessel;	Filter 105 is mounted in a collapsed state within a distal end of catheter 118 and delivered to a deployment site in a vessel (page 26, lines 12-13).
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	When the filter is correctly positioned "the catheter 118 is retracted allowing the support frame to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall; however, the openings or pores in the net are sized so as to retain the embolic material." (page 26, lines 13-18).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	When the filter has been deployed in a blood vessel, the catheter can be removed leaving a bare guidewire proximal to the filter for use with known devices such as balloon catheter and stent devices upstream of the filter (page 27, lines 13-15).

rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9, lines 28-30).
further comprising:	
providing a retrieval catheter having a pod;	The tip of the catheter which forms a housing or pod for reception of the filter is of an elastic material which can radially expand to accommodate the filter with the captured embolic material. . . . when retrieving the fitter, the catheter tip or pod is sufficiently elastic to accommodate the extra bulk of the filter due to the embolic material (page 26, line 31 to page 27, line 3).
advancing the retrieval catheter over the guide wire until the pod covers a mouth of the filter element; and urging the retrieval catheter against the self-expanding struts of the filter element to cause the filter element to collapse.	After use the catheter is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet end 112 first to close the openings and then gradually collapsing the net against the sleeve 104 as the catheter 118 advances over the filter 105 (page 26, lines 18-22).

VII. Statement Pursuant to 37 C.F.R. §41.202(a)(6)

The present application is a continuation of Application Ser. No. 09/921,596, filed on August 6, 2001 (now U.S. Patent No. 6,432,122), which is a continuation of Application Ser. No. 09/188,472, filed on Nov. 9, 1998 (now U.S. Patent 6,336,934). The disclosure of the present application is thus the same as the disclosure of the parent and grandparent applications, and Applicants are entitled at least to benefit of the filing date of grandparent Application Ser. No. 09/188,472, filed on Nov. 9, 1998, as a constructive reduction to practice of the subject matter of each proposed count.

A. Constructive Reduction to Practice of Count 1 by Applicants' Prior U.S. Patent Applications

Pursuant to 37 C.F.R. §41.202(a)(6), Applicants provide a chart showing where the disclosure of Applicants' parent Application Ser. No. 09/921,596 and grandparent application Ser. No. 09/188,472 each provides a constructive reduction to practice of an embodiment anticipating proposed Count 1.

Proposed Count 1 (Gilson Claim 97)	**Disclosure of Ser. No. 09/921,596 and Ser. No. 09/188,472**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	Filter 105 shown in Figs. 40-42 is positioned in a vessel, and filters emboli from blood flowing through the net wall (page 26, lines 12-18), using the device 100 comprising:
providing a guide wire having a distal stop,	Guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-9), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17).

and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	The capture ring is tubular sleeve 104, which is slidably mounted on the guidewire 101, and collapsible filter 105 is mounted on the sleeve 104 (page 25, lines 8-13).
transluminally inserting the guide wire and filter element into a vessel;	Filter 105 is mounted in a collapsed state within a distal end of catheter 118 and delivered to a deployment site in a vessel (page 26, lines 12-13).
deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	When the filter is correctly positioned "the catheter 118 is retracted allowing the support frame to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall; however, the openings or pores in the net are sized so as to retain the embolic material." (page 26, lines 13-18).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	When the filter has been deployed in a blood vessel, the catheter can be removed leaving a bare guidewire proximal to the filter for use with known devices such as balloon catheter and stent devices upstream of the filter (page 27, lines 13-15).
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element.	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter

	position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9, lines 28-30).

Pursuant to 37 C.F.R. §41.202(a)(6), Applicants provide the following chart showing where the disclosure of Applicants' parent Application Ser. No. 09/921,596 and grandparent application Ser. No. 09/188,472 each provides a constructive reduction to practice of another embodiment anticipating proposed Count 1.

Proposed Count 1 (Gilson Claim 97)	**Disclosure of Ser. No. 09/921,596 and Ser. No. 09/188,472**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	The embolic protection device according to the invention is placed in a vessel and "provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure" (page 15, line 31 to page 16, line 1).
providing a guide wire having a distal stop,	Fig. 28: stopper 64 is mounted on the distal region of primary guidewire 2 (page 21, line 33 to page 22, line 7).
and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	Fig. 28: substrate 33 is a capture ring on which filter element 1 is mounted, and which translates between stoppers 63 and 64 (page 22, lines 5-7) proximal of stopper 64. Fig. 30: when the filter element is in its most distal position on guidewire 2 (arrow), stopper 64 prevents the filter element 1 from moving beyond it in the distal direction (page 22, line 32 to page 23, line 1).
transluminally inserting the guide wire and filter element into a vessel;	the embolic protection device may be used in an over the wire transcatheter configuration, in which the clinician crosses the lesion with a

	steerable guidewire, and the protection device is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 16, lines 6-9).
deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	the self-expanding embolic protection device is deployed in a vessel and "provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure" (page 15, line 31 to page 16, line 1).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	the embolic protection device is placed distal to the site of the lesion being treated and will capture emboli that are generated or dislodged during balloon inflation and stent placement (page 16, lines 6-11), which are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 16, lines 6-11; page 21, lines 27-29; claims 23, 24).
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element.	Fig. 28: The filter element 1 mounted between stoppers 63 and 64 "can move axially and rotationally independently of the guidewire. . . . The filter position will be maintained during the exchange of catheters." (page 22, lines 11-13). This "facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter." (page 9, lines 28-30).

B. Constructive Reduction to Practice of Count 2 by Applicants' Prior U.S. Patent Applications

Pursuant to 37 C.F.R. §41.202(a)(6), Applicants provide the following chart showing where the disclosure of Applicants' parent Application Ser. No. 09/921,596 and grandparent

application Ser. No. 09/188,472 each provides a constructive reduction to practice of an embodiment anticipating proposed Count 2.

Proposed Count 2 (Gilson Claim 98)	**Disclosure of Ser. No. 09/921,596 and Ser. No. 09/188,472**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	Filter 105 shown in Figs. 40-42 is positioned in a vessel, and filters emboli from blood flowing through the net wall (page 26, lines 12-18), using the device 100 comprising:
providing a guide wire having a distal region including a distal stop,	A guidewire 101 with a proximal end 102 and a distal end 103 (page 25, lines 7-9), wherein "the sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101" (page 25, lines 15-17).
and a filter element disposed for translation on the guide wire proximal to the distal stop,	Collapsible filter 105 is mounted on tubular sleeve 104, which is slidably mounted on the guidewire 101 proximal to stop 107 (page 25, lines 10-13).
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	The filter 105 comprises a mesh net 110 mounted over a collapsible support frame 111 which is naturally expanded (page 25, lines 19-29) and expands when the delivery catheter is retracted (page 26, lines 12-15); as shown in Fig. 18, collapsible filter support element 50 has a number of foldable arms 51 which collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel (page 20, line 33 to page 21, line 3); the membrane filter fabric may be bonded to the supporting spoke framework (page 19, lines 6-11) or attached over the Nitinol frame

	(page 20, lines 3-8).
transluminally inserting the guide wire and filter element into a vessel;	Filter 105 is mounted in a collapsed state within a distal end of catheter 118 and delivered to a deployment site in a vessel (page 26, lines 12-13).
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	When the filter is correctly positioned "the catheter 118 is retracted allowing the support frame to expand inflating the net 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the net 110. The blood will pass through the net wall; however, the openings or pores in the net are sized so as to retain the embolic material." (page 26, lines 13-18).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	When the filter has been deployed in a blood vessel, the catheter can be removed leaving a bare guidewire proximal to the filter for use with known devices such as balloon catheter and stent devices upstream of the filter (page 27, lines 13-15).
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	The filter is not fast on the guidewire and thus accidental movement of the guidewire is accommodated without unintentionally moving the filter, for example during exchange of medical devices or when changing catheters (page 27, lines 5-7); the filter element is mounted on a guidewire such that the guidewire has freedom to rotate and/or move axially independently of the filter, and more preferably the wire has complete freedom to rotate independently of the filter and has limited axial movement (page 9, lines 22-25), which facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter (page 9,

	lines 28-30).
further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	Fig. 42: retraction of the guide wire 101 in a proximal direction causes distal stop 107 to abut against tubing substrate 104 (as shown retracted from position in Fig. 41). At the end of the procedure, a sheath is advanced to the proximal end of the device, and the filter is pulled proximally into it (page 20, lines 20-22), by retracting the guidewire, which is the only way to pull the filter shown in Figs. 41 and 42 proximally into the retrieval catheter.

Pursuant to 37 C.F.R. §41.202(a)(6), Applicants provide the following chart showing where the disclosure of Applicants' parent Application Ser. No. 09/921,596 and grandparent application Ser. No. 09/188,472 each provides a constructive reduction to practice of another embodiment anticipating proposed Count 2.

Proposed Count 2 (Gilson Claim 98)	**Disclosure of Ser. No. 09/921,596 and Ser. No. 09/188,472**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	The embolic protection device according to the invention is placed in a vessel and "provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure" (page 15, line 31 to page 16, line 1).
providing a guide wire having a distal region including a distal stop,	Fig. 28: stopper 64 is mounted on the distal region of primary guidewire 2 (page 21, line 33 to page 22, line 7).
and a filter element disposed for translation on the guide wire proximal to the distal stop,	Fig. 28: filter element 1 is mounted on substrate 33, which translates between stoppers 63 and 64 on the guidewire proximal to the distal stop (page 22, lines 5-7).

the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	As shown in Fig. 18, collapsible filter support element 50 has a number of foldable arms 51 which collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel (page 20, line 32 to page 21, line 3); the membrane filter fabric may be bonded to the supporting spoke framework (page 19, lines 6-11) or attached over the Nitinol frame (page 20, lines 3-8).
transluminally inserting the guide wire and filter element into a vessel;	The embolic protection device may be used in an over the wire transcatheter configuration, in which the clinician crosses the lesion with a steerable guidewire, and the protection device is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 16, lines 6-9).
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	The embolic protection device is placed in a vessel and "provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure" (page 15, line 31 to page 16, line 1).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	The embolic protection device is placed distal to the site of the lesion being treated and will capture emboli that are generated or dislodged during balloon inflation and stent placement (page 16, lines 6-11), which are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 16, lines 6-11; page 21, lines 27-29; claims 23, 24).
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	Fig. 28: The filter element 1 mounted between stoppers 63 and 64 "can move axially and rotationally independently of the guidewire.. . . The filter position will be maintained during the exchange of catheters." (page 22, lines 11-

	13). This "facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter." (page 9, lines 28-30).
further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	In Fig. 30, the filter is deployed, and the guidewire 2 is retracted such that the distal stop 64 abuts against the sleeve 33 of filter element 1. At the end of the procedure, a sheath is advanced to the proximal end of the device, and the filter is pulled proximally into it (page 20, lines 20-22), by retracting the guidewire, which is the only way to pull the filter shown in Figs. 30 and 31 proximally into the retrieval catheter.

C. Constructive Reduction to Practice of Count 1 by Applicants' Irish Priority Application No. 98 0267

Pursuant to 37 C.F.R. §41.202(a)(6), Applicants provide a chart showing where the disclosure of Applicants' Irish Priority Application No. 98 0267, filed April 8, 1998, provides a constructive reduction to practice of an embodiment anticipating proposed Count 1.

Proposed Count 1 (Gilson Claim 97)	**Disclosure of Irish Application No. 98 0267**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	The embolic protection device according to the invention is placed in a vessel and "provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure" (page 13, lines 5-10).
providing a guide wire having a distal stop	Fig. 28: stopper 64 is mounted on the distal region of primary guidewire 2 (page 21, lines 5-13).

and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;	Fig. 28: substrate 33 is a capture ring on which filter element 1 is mounted, and which translates between stoppers 63 and 64 proximal of stopper 64 (page 21, lines 5-7). Fig. 30: when the filter element is in its most distal position on guidewire 2 (arrow), stopper 64 prevents the filter element 1 from moving beyond it in the distal direction (page 21, lines 36-39).
transluminally inserting the guide wire and filter element into a vessel;	The embolic protection device may be used in an over the wire transcatheter configuration, in which the clinician crosses the lesion with a steerable guidewire, and the protection device is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 13, lines 17-22).
deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;	The embolic protection device is placed in a vessel and "provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure" (page 13, lines 5-10).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	The embolic protection device is placed distal to the site of the lesion being treated and will capture emboli that are generated or dislodged during balloon inflation and stent placement (page 13, lines 19-25), which are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 13, lines 19-25; page 20, lines 23-25; claims 23, 24).
rotation or distal translation of the guide wire relative to the filter element device not displacing the filter element.	Fig. 28: The filter element 1 mounted between stoppers 63 and 64 "can move axially and rotationally independently of the guidewire. . . . The filter position will be maintained during the exchange of catheters." (page 21, lines 17-

	19). This "facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter." (page 7, lines 25-27).

D. Constructive Reduction to Practice of Count 2 by Applicants' Irish Priority Application No. 98 0267

Pursuant to 37 C.F.R. §41.202(a)(6), Applicants provide a chart showing where the disclosure of Applicants' Irish Priority Application No. 98 0267, filed April 8, 1998, provides a constructive reduction to practice of an embodiment anticipating proposed Count 2.

Proposed Count 2 (Gilson Claim 98)	**Disclosure of Irish Application No. 98 0267**
A method of filtering emboli from blood flowing through a vessel, the method comprising:	The embolic protection device according to the invention is placed in a vessel and "provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure" (page 13, lines 5-10).
providing a guide wire having a distal region including a distal stop,	Fig. 28: stopper 64 is mounted on the distal region of primary guidewire 2 (page 21, lines 5-13).
and a filter element disposed for translation on the guide wire proximal to the distal stop,	Fig. 28: filter element 1 is mounted on substrate 33, which translates between stoppers 63 and 64 on the guidewire proximal to the distal stop (page 21, lines 5-7).
the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto;	As shown in Fig. 18, collapsible filter support element 50 has a number of foldable arms 51 which collapse against the shaft 33 for deployment and upon release extend outwardly to expand the filter 1 in the vessel

	(page 19, lines 25-32); the membrane filter fabric may be bonded to the supporting spoke framework (page 15, lines 25-31) or attached over the Nitinol frame (page 17, lines 6-7).
transluminally inserting the guide wire and filter element into a vessel;	The embolic protection device may be used in an over the wire transcatheter configuration, in which the clinician crosses the lesion with a steerable guidewire, and the protection device is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 13, lines 17-22).
deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;	The embolic protection device is placed in a vessel and "provides a pathway for blood and has means for capturing and retaining undesired embolic material released during the surgical procedure" (page 13, lines 5-10).
advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,	The embolic protection device is placed distal to the site of the lesion being treated and will capture emboli that are generated or dislodged during balloon inflation and stent placement (page 13, lines 19-25), which are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 13, lines 19-25; page 20, lines 23-25; claims 23, 24).
rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;	Fig. 28: The filter element 1 mounted between stoppers 63 and 64 "can move axially and rotationally independently of the guidewire. . . . The filter position will be maintained during the exchange of catheters." (page 21, lines 17-19). This "facilitates the maintenance of filter position during the exchange of catheters and permits the steering of the wire independent of the filter." (page 7, lines 25-27). In Fig. 30, the filter is deployed, and the

further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.	guidewire 2 is retracted such that the distal stop 64 abuts against the sleeve 33 of filter element 1. At the end of the procedure, a sheath is advanced to the proximal end of the device, and the filter is pulled proximally into it (page 19, lines 18-20), by retracting the guidewire, which is the only way to pull the filter shown in Figs. 30 and 31 proximally into the retrieval catheter.

Each of applicants U.S. Application Ser. No. 09/921,596 and Ser. No. 09/188,472, and Irish Application No. 98 0267 disclose various embodiments, each of which anticipates proposed Count 1 and proposed Count 2, and each of these applications thus constitutes a constructive reduction to practice of both proposed counts.

VIII. CONCLUSION

Applicants request that an interference be declared between the present application and Broome *et al.* U.S. Patent Application Serial No. 09/723,003, and that the Broome *et al.* application be withdrawn from issuance, if necessary, for declaration of the interference.

In an interference between the present application and Broome *et al.* Application Serial No. No. 09/723,003, the present Applicants should be designated as senior party, by virtue of their earlier constructive reduction to practice of the subject matter of each count, for the reasons stated above.

Respectfully submitted,

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